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# Improving Quality of Patient Data for Treatment of Multidrug- or Rifampin-Resistant Tuberculosis

## Appendix

## Data Dictionary for MDR/RR TB IPD

The tables within this section pertain to the data elements optimally preferred for collection during the conduct of observational studies or in routinely collected programmatic data, along with their requested coding to ensure uniformity across studies. Caveats and additional information on specific elements are contained within the main text of the online report.

| Facility Information | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| COUNTRY | Country | Country of the primary source | Char | | |
| TREATING_SITE | Treating Site Name | Name of the primary source | Char | | |
| SITE_ID | Treating Site Identifier | Site ID number | Char | | |

| Patient Identifier and Demographics | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| PATIENT_ID | Patient Identifier | Patient ID number in country database | Char | | |
| YEAR | Year | Year of treatment start for this episode | Num ### | | |
| AGE | Age | Age of the patient in years | Num ### | | |
| SEX | Sex | Patient's biologic sex at birth | Category | F | Female |
| | | | | M | Male |
| | | | | U | Unknown |
| WEIGHT | Weight | Patient's weight in kilograms | Num ### | | |
| HEIGHT | Height | Patient's height in centimeters | Num ### | | |
| BMI | Body Mass Index | Patient's body mass index in kilograms per meters-squared | Num ### | | |

| Patient Baseline Characteristics | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| SMOKINGSTATUS | Smoking Status | The patient's smoking status at start of treatment | Category | Current | Current Smoker |
| | | | | Ex | Ex-Smoker |
| | | | | Never | Never Smoker |
| | | | | U | Unknown |
| SMOKINGPACKPERDAY | Packs Smoked Per Day | Total number of packs per day smoked at start of treatment (if current smoker) | Num ### | | |
| SMOKINGTOTALPACKYEAR | Total Pack Years | Total number of pack years smoked (if current- or ex-smoker) | Num ### | | |
| ALCOHOL | Alcohol Use | Does the patient drink (defined as ≥1 drink per week in men or women) | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| ALCOHOLABUSE | Alcohol Abuse Disorder | If the patient drinks, do they meet the definition of alcohol abuse (≥14 drinks per week in men or ≥7 drinks per week in women) | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| DM | Diabetes Mellitus | Is the patient diagnosed with diabetes? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| INSULINDEPENDENT | Type 1 Diabetes Mellitus | Is the patient insulin dependent (if having diabetes)? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| HBA1C | Hemoglobin A1c Level | Patients HbA1c measure defined in percent (%) | Num ### | | |
| RENALFAILURE | Presence of Renal Failure | Does the patient have renal failure? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| HEPB | Hepatitis B | Does the patient have hepatitis B? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| HEPC | Hepatitis C | Does the patient have hepatitis C? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| OTHERLIVER | Other Liver Condition | Does the patient have liver conditions other than hepatitis B or hepatitis C? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| HIV | HIV | What is the patient's HIV status? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | U | Unknown |
| HIV_DIAGNOSISYEAR | Year HIV Diagnosed | If the patient is HIV-positive, the year HIV was diagnosed | Num ### | | |
| CD4 | CD4 Count | If the patient is HIV-positive, what is their CD4 count at treatment start (cells/μL)? | Num ### | | |
| VIRALLOAD | Viral Load | If the patient is HIV-positive, what is their viral load at treatment start (copies/ml) | Num ### | | |
| ART | Use of Antiretroviral Treatment | If the patient is HIV-positive, are they on antiretroviral treatment? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| ART_STARTYEAR | Year Antiretroviral Treatment Started | If the patient is on antiretroviral treatment, what year did they start? | Num ### | | |
| ART_REGIMEN | Antiretroviral Treatment Regimen | What is the antiretroviral treatment regimen?<br>List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |

| Previous Treatment Information | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| PASTTX | Previous Treatment | Has the patient ever received tuberculosis treatment for >30 d? | Category | Y | Yes |
| | | | | N | No |
| RECEIVEDFLD | Previous Treatment with First-Line Drugs | If the patient has received previous tuberculosis treatment, was treatment with first-line drugs given for >30 d? | Category | Y | Yes |
| | | | | N | No |
| RECEIVEDSLD | Previous Treatment with Second-Line Drugs | If the patient has received previous tuberculosis treatment, was treatment with second-line drugs given for >30 d? | Category | Y | Yes |
| | | | | N | No |
| YEARPASTTX1* | Year of Most Recent Previous Treatment | The year the patient most recently received previous tuberculosis treatment | Num ### | | |
| REGIMENPASTTX1* | Regimen Used for Most Recent Previous Treatment | The drug-regimen given to the patient during the most recent previous tuberculosis treatment. List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| OUTPASTTX1* | End-of-Treatment Outcome for Most Recent Previous Treatment | The end-of-treatment outcome recorded for the patient at the end of their most recent previous tuberculosis treatment. | Category | Cure | Cure |
| | | | | Complete | Completed Treatment |
| | | | | Fail | Treatment Failure |
| | | | | Lost | Lost to Follow-up |
| | | | | U | Unknown |
| YEARPASTTX2* | Year of Second-Most Recent Previous Treatment | The year the patient received previous tuberculosis treatment for their second-most recent treatment episode. | Num ### | | |
| REGIMENPASTTX2* | Regimen Used for Second-Most Recent Previous Treatment | The drug-regimen given to the patient during the second-most recent previous tuberculosis treatment. List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| OUTPASTTX2* | End-of-Treatment Outcome for Second-Most Recent Previous Treatment | The end-of-treatment outcome recorded for the patient at the end of their second-most recent previous tuberculosis treatment. | Category | Cure | Cure |
| | | | | Complete | Completed Treatment |
| | | | | Fail | Treatment Failure |
| | | | | Lost | Lost to Follow-up |
| | | | | U | Unknown |
| *Fields need to be completed only if previous treatment has been administered. | | | | | |

| Disease Characteristics | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| DISEASE_SITE | Site of Tuberculosis Disease | The site of tuberculosis disease diagnosed in the patient | Category | PTB | Pulmonary TB |
| | | | | EPTB | Extrapulmonary TB |
| | | | | Both | Both |
| EXTRAPULM_SITE | Primary Site of Extrapulmonary Tuberculosis | If extrapulmonary tuberculosis is diagnosed, the primary site affected | Category | Miliary | Miliary TB |
| | | | | Genital | Genitourinary TB |
| | | | | CNS | Central Nervous System TB |
| | | | | Periton | TB Peritonitis |
| | | | | Pericar | TB Pericarditis |
| | | | | Lymph | TB Lymphadenitis |
| | | | | Pleural | Pleural TB |
| | | | | GI | Gastrointestinal TB |
| | | | | Bone | Bone TB |
| | | | | Joint | Joint TB |
| | | | | Other | Other |
| CAVITATION_BASE* | Lung Cavitation | Was there presence of lung cavitation on chest x-ray at treatment start? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| BILATERAL_BASE* | Bilateral Disease | Was there presence of bilateral disease on chest X-ray at treatment start? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| AFB_BASE | Acid-Fast Bacilli Smear Result | What was the patient's acid-fast bacilli smear result (taken ≤1 mo after treatment start)? Consider all samples taken over this time frame and consider positive if any were positive (i.e., scanty or greater). | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_BASE | Sputum Culture Result | What was the patient's sputum culture result (taken ≤1 mo after treatment start)? Consider all samples taken over this frame and consider positive if any were positive. | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTUREMEDIA | Culture Media Used | If culture was done, what media was used for the result reported? | Category | Solid | Solid Media |
| | | | | Liquid | Liquid Media |
| *Baseline refers to any evidence of cavitation or bilateral disease within 30 d of treatment start. | | | | | |

| Genotypic DST | | | | | |
|---|---|---|---|---|---|
| **Field*** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| GENOTYPIC_USED | Genotypic DST Used | Were genotypic DST techniques used? | Category | Y | Yes |
| | | | | N | No |
| XPERT_BASE | Gene Xpert Used | Was Gene Xpert used for diagnosis? | Category | Y | Yes |
| | | | | N | No |
| DATE_XPERT | Date of Gene Xpert | Date of Gene Xpert used for diagnosis <mm/dd/yy> | Date | | |
| XPERT_MTBRESULT_BASE | Gene Xpert MTB Result | What was the result for MTB on Gene Xpert? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| XPERT_RIFRESULT_BASE | Gene Xpert Rifampin Resistance Result | What was the result for rifampin resistance on Gene Xpert? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| FIRSTLINE_LPA_BASE | First-Line LPA Used | Was first-line LPA used after TB diagnosis? | Category | Y | Yes |
| | | | | N | No |
| DATE_FIRSTLINE_LPA | Date of First-Line LPA | Date of first-line LPA used after TB diagnosis <mm/dd/yy> | Date | | |
| FIRSTLINE_LPA_MTB_BASE | First-Line LPA MTB Result | What was the result for MTB on first-line LPA? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| FIRSTLINE_LPA_H_BASE | First-Line LPA Isoniazid Resistance Result | What was the result for isoniazid resistance on first-line LPA? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| FIRSTLINE_LPA_R_BASE | First-Line LPA Rifampin Resistance Result | What was the result for rifampin resistance on first-line LPA? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| SECONDLINE_LPA_BASE | Second-Line LPA Used | Was second-line LPA performed after TB diagnosis? | Category | Y | Yes |
| | | | | N | No |
| DATE_SECONDLINE_LPA | Date of Second-Line LPA | Date of second-line LPA used after TB diagnosis <mm/dd/yy> | Date | | |
| SECONDLINE_LPA_MTB_BASE | Second-Line LPA MTB Result | What was the result for MTB on second-line LPA? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| SECONDLINE_LPA_SLI_BASE | Second-Line LPA Second-Line Injectable Resistance Result | What was the result for second-line injectable resistance on second-line LPA? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| SECONDLINE_LPA_FQ_BASE | Second-Line LPA Fluoroquinolone Resistance Result | What was the result for fluoroquinolone resistance on second-line LPA? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |

*Baseline DST refers to any sample taken within 90 d of treatment start, up to 30 d after treatment start. Every effort should be made to have reliable DST results; if genotypic tests are not used, phenotypic tests should be performed. If genotypic techniques for detection other than those listed in this table are in use (e.g., *pncA* for pyrazinamide), they may be appended to this section in a similar format (e.g., Test Done, Date of Test, Results of Test).

| Phenotypic DST | | | | | |
|---|---|---|---|---|---|
| **Field*** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| PHENODST | Phenotypic DST Done | Was phenotypic DST performed? | Category | Y | Yes |
| | | | | N | No |
| DATE_PHENODST | Date of Phenotypic DST | Date of phenotypic DST done after TB diagnosis <mm/dd/yy> | Date | | |
| DST_H_BASE | Isoniazid Resistance Result | What was the result for isoniazid resistance (MIC >0.1–0.2 μg/ml on MGIT) on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_HIGHH_BASE | High-Level Isoniazid Resistance Result | What was the result for high-level isoniazid resistance (MIC >1–2 μg/ml on MGIT) on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_R_BASE | Rifampin Resistance Result | What was the result for rifampin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_E_BASE | Ethambutol Resistance Result | What was the result for ethambutol resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_Z_BASE | Pyrazinamide Resistance Result | What was the result for pyrazinamide resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_AM_BASE | Amikacin Resistance Result | What was the result for amikacin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_KM_BASE | Kanamycin Resistance Result | What was the result for kanamycin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_CM_BASE | Capreomycin Resistance Result | What was the result for capreomycin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_OFX_BASE | Ofloxacin Resistance Result | What was the result for ofloxacin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_CFX_BASE | Ciprofloxacin Resistance Result | What was the result for ciprofloxacin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_MFX_BASE | Moxifloxacin Resistance Result | What was the result for moxifloxacin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_LFX_BASE | Levofloxacin Resistance Result | What was the result for levofloxacin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_S_BASE | Streptomycin Resistance Result | What was the result for streptomycin resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_ETO_BASE | Ethionamide Resistance Result | What was the result for ethionamide resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_PTO_BASE | Prothionamide Resistance Result | What was the result for prothionamide resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |

| Phenotypic DST | | | | | |
|---|---|---|---|---|---|
| **Field*** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| | | | | ND | Not Done |
| DST_CS_BASE | Cycloserine Resistance Result | What was the result for cycloserine resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_TRD_BASE | Terizidone Resistance Result | What was the result for terizidone resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_PAS_BASE | Para-Amino-Salicylic Acid Resistance Result | What was the result for para-amino-salicylic acid resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_LZD_BASE | Linezolid Resistance Result | What was the result for linezolid resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_CFZ_BASE | Clofazimine Resistance Result | What was the result for clofazimine resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_BDQ_BASE | Bedaquiline Resistance Result | What was the result for bedaquiline resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| DST_DLM_BASE | Delamanid Resistance Result | What was the result for delamanid resistance on phenotypic DST? | Category | R | Resistant |
| | | | | S | Susceptible |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| *Baseline DST refers to any sample taken within 90 d of treatment start, up to 30 d after treatment start. Additional drugs for which phenotypic DST is available can be reported (e.g., Pretomanid). Within all shared data, the method and critical concentration used for each drug must be recorded. | | | | | |

| Follow-Up DST and Acquired Drug Resistance | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| FOLLOWUP_DST | Follow-up DST Performed | Was there follow-up DST performed? | Category | Y | Yes |
| | | | | N | No |
| FOLLOWUPDST1_DATE* | Date of First Follow-up DST | Date of first follow-up DST <mm/dd/yy> | Date | | |
| FOLLOWUPDST_RES1 | Resistant Isolates on First Follow-up DST | List newly discovered resistances not found on baseline DST, due to missingness or baseline susceptibility. If none discovered, list "no change in DST."<br>List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| FOLLOWUPDST_SUS1 | Susceptible Isolates on First Follow-up DST | List newly discovered susceptible drugs not found on baseline DST, due to missingness or baseline resistance. If none discovered, list "no change in DST."<br>List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| ACQUIRED_RESISTANCE† | Acquired Drug Resistance | List the drugs that the strain was shown to acquire resistance to during any follow-up DST (defined as previously identified susceptibility and subsequent resistance on follow-up DST).<br>List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |

*Additional follow-up DST results can be entered following a similar format.
†Acquired resistance can be reported in a separate row but is not necessary as it can be calculated by the data analyst with the above collected data.

| Regimen Information* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| STARTINGREGIMENTYPE | Regimen Type at Start of Treatment | List the starting regimen type: short (intended duration ≤12 mo) or long (intended duration ≥18 mo) | Category | Short | Short Regimen |
| | | | | Long | Long Regimen |
| TXSTART_DATE | Treatment Start Date | Date of second-line drug initiation in this treatment episode <mm/dd/yy> | Date | | |
| INITIAL_REGIMEN | Starting Treatment Regimen | List the drugs the patient is on at the start of treatment. List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| H_START | Isoniazid Start Date | Date standard-dose isoniazid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| H_STOP | Isoniazid End Date | Date standard-dose isoniazid was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| HIGHH_START | High-Dose Isoniazid Start Date | Date high-dose isoniazid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| HIGHH_STOP | High-Dose Isoniazid End Date | Date high-dose isoniazid was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| E_START | Ethambutol Start Date | Date ethambutol was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| E_STOP | Ethambutol End Date | Date ethambutol was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| Z_START | Pyrazinamide Start Date | Date pyrazinamide was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| Z_STOP | Pyrazinamide End Date | Date pyrazinamide was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| S_START | Streptomycin Start Date | Date streptomycin isoniazid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| S_STOP | Streptomycin End Date | Date streptomycin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| RFB_START | Rifabutin Start Date | Date rifabutin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| RFB_STOP | Rifabutin End Date | Date rifabutin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| AM_START | Amikacin Start Date | Date amikacin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| AM_STOP | Amikacin End Date | Date amikacin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| KM_START | Kanamycin Start Date | Date kanamycin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| KM_STOP | Kanamycin End Date | Date kanamycin was permanently removed from the patient's regimen | Date | | |

| Regimen Information* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| | | <mm/dd/yy> | | | |
| CM_START | Capreomycin Start Date | Date capreomycin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| CM_STOP | Capreomycin End Date | Date capreomycin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| OFX_START | Ofloxacin Start Date | Date ofloxacin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| OFX_STOP | Ofloxacin End Date | Date ofloxacin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| CFX_START | Ciprofloxacin Start Date | Date ciprofloxacin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| CFX_STOP | Ciprofloxacin End Date | Date ciprofloxacin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| MFX_START | Moxifloxacin Start Date | Date moxifloxacin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| MFX_STOP | Moxifloxacin End Date | Date moxifloxacin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| LFX_START | Levofloxacin Start Date | Date levofloxacin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| LFX_STOP | Levofloxacin End Date | Date levofloxacin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| GFX_START | Gatifloxacin Start Date | Date gatifloxacin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| GFX_STOP | Gatifloxacin End Date | Date gatifloxacin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| SFX_START | Sparfloxacin Start Date | Date sparfloxacin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| SFX_STOP | Sparfloxacin End Date | Date sparfloxacin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| ETO_START | Ethionamide Start Date | Date ethionamide was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| ETO_STOP | Ethionamide End Date | Date ethionamide was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| PTO_START | Prothionamide Start Date | Date prothionamide was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| PTO_STOP | Prothionamide End Date | Date prothionamide was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| CS_START | Cycloserine Start Date | Date cycloserine was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| CS_STOP | Cycloserine End Date | Date cycloserine was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| TRD_START | Terizidone Start Date | Date terizidone was introduced into the patient's regimen. <mm/dd/yy> | Date | | |

| Regimen Information* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| TRD_STOP | Terizidone End Date | Date terizidone was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| PAS_START | Para-Aminosalicylic Acid Start Date | Date para-aminosalicylic acid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| PAS_STOP | Para-Aminosalicylic Acid End Date | Date para-aminosalicylic acid was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| LZD_START | Linezolid Start Date | Date linezolid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| LZD_STOP | Linezolid End Date | Date linezolid was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| CFZ_START | Clofazimine Start Date | Date clofazimine was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| CFZ_STOP | Clofazimine End Date | Date clofazimine was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| AMXCLV_START | Amoxicillin and Clavulanic Acid Start Date | Date amoxicillin and clavulanic acid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| AMXCLV_STOP | Amoxicillin and Clavulanic Acid End Date | Date amoxicillin and clavulanic acid was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| IPM_START | Imipenem-Cilastatin Start Date | Date imipenem-cilastatin was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| IPM_STOP | Imipenem-Cilastatin End Date | Date imipenem-cilastatin was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| MPM_START | Meropenem Start Date | Date meropenem was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| MPM_STOP | Meropenem End Date | Date meropenem was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| BDQ_START | Bedaquiline Start Date | Date bedaquiline was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| BDQ_STOP | Bedaquiline End Date | Date bedaquiline was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| DLM_START | Delamanid Start Date | Date delamanid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| DLM_STOP | Delamanid End Date | Date delamanid was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| PA_START | Pretomanid Start Date | Date pretomanid was introduced into the patient's regimen. <mm/dd/yy> | Date | | |
| PA_STOP | Pretomanid End Date | Date pretomanid was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| PCZ_START | Perchlozone Start Date | Date perchlozone was introduced into the patient's regimen. <mm/dd/yy> | Date | | |

| Regimen Information* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| PCZ_STOP | Perchlozone End Date | Date perchlozone was permanently removed from the patient's regimen <mm/dd/yy> | Date | | |
| TXEND_DATE | Treatment End Date | Date treatment ended in this treatment episode <mm/dd/yy> | Date | | |
| DURATION_CHANGE | Intended Duration of Regimen Changed | If the patient started on a short regimen, did they switch to a long regimen? | Category | Y | Yes |
| | | | | N | No |
| CHANGE_DATE | Date of Regimen Duration Change | The date the patient changed from a short regimen to a long regimen <mm/dd/yy> | Date | | |
| CHANGE_REASON | Reason the Regimen Duration Changed | What was the reason the regimen duration changed? This may include: in response to drug susceptibility testing, treatment non-response, drug availability, drug tolerability, or other. | Category | DST | Drug Resistance |
| | | | | NoResp | Non-Response |
| | | | | AE | Tolerability |
| | | | | Avail | Drug Availability |
| | | | | Other | Other |
| *For drugs not used in the regimen, their coding can remain blank. Stop dates must refer to the date that the drug was permanently withdrawn from the regimen. New rows can be added to accommodate drugs not contained in this table. | | | | | |

| Treatment Information | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| TXDUR_DAYS | Treatment Duration | Total number of days of treatment, from first to last dose taken | Num ### | | |
| DOT | Directly Observed Therapy | Was directly observed therapy used? | Category | Y | Yes |
| | | | | N | No |
| DOT_TYPE | Type of Directly Observed Therapy | State the type of directly observed therapy used. Virtual includes methods such as video, mobile text, or medication monitoring, among others. | Category | Comm | Community |
| | | | | Hosp | Hospital |
| | | | | Pharm | Pharmacy |
| | | | | Virtual | Virtual |
| DOT_FREQUENCY | Frequency of DOT Visits | How many days per week is DOT provided to the patient (range 0–7 d) | Num ### | | |
| SUPPORT | Patient Support Provided | What form of patient support was provided to patients? This may include support from employers (job security), nutritional support, financial support, or others. If more than one form, please select multiple. | Category | Employ | Employment |
| | | | | Nutri | Nutritional |
| | | | | Finance | Financial |
| | | | | Other | Other |
| | | | | Multi | Multiple |
| | | | | None | None |

| Surgery and Hospitalization Information | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| SURGERY | Lung Resection Surgery | Did the patient have lung resection surgery related to MDR/RR-TB? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| SURGTYPE | Type of Lung Resection Surgery | What was the type of lung resection surgery? | | Lobe | Lobectomy |
| | | | | Pneu | Pneumonectomy |
| | | | | Wedge | Wedge Resection |
| | | | | Other | Other |
| | | | | U | Unknown |
| SURG_DATE | Date of Surgery | What was the date of surgery? | Date | | |
| HOSP | Hospitalization | Was the patient hospitalized at any point during treatment? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| HOSPEPISODES | Number of Hospitalization Episodes | What is the total number of hospitalization episodes during treatment? | Num ### | | |
| HOSPDUR_DAYS | Total Hospitalization Duration | What is the total duration of hospitalization during treatment? | Num ### | | |

| Adverse Event Information | | | | | |
|---|---|---|---|---|---|
| **Field*** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| AE1 | First Adverse Event | Did the patient experience a serious adverse event and/or permanently stop the drug | Category | SAE | Serious Adverse Event |
| | | | | Perm | Permanent Stop |
| | | | | Both | Both |
| AE1_DATE | Date of First Adverse event | What was the date of the permanent discontinuation of the drug(s)? | Date | | |
| AE1_DRUG | Drug Responsible for First Adverse Event | List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| AE1_GRADE | Grade of First Adverse Event | What was the grade of the first adverse event? | Num ### | | |
| AE1_SYSTEMORGAN | System / Organ Class Affected by First Adverse Event | Which system / organ classes were affected by the first adverse event? List each system / organ class, separated by a comma, using the list provided with this dictionary. | Char | | |
| AE1_OUTCOME | Outcome of First Adverse Event | What was the outcome of the first adverse event? | Category | Recov | Recovered |
| | | | | NoRecov | Not Recovered |
| | | | | Died | Died |
| | | | | U | Unknown |
| AE2 | Second Adverse Event | Did the patient experience a serious adverse event and/or permanently stop the drug | Category | SAE | Serious Adverse Event |
| | | | | Perm | Permanent Stop |
| | | | | Both | Both |
| AE2_DATE | Date of Second Adverse event | What was the date of the permanent discontinuation of the drug(s)? | Date | | |
| AE2_DRUG | Drug Responsible for Second Adverse Event | List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| AE2_GRADE | Grade of Second Adverse Event | What was the grade of the second adverse event? | Num ### | | |
| AE2_SYSTEMORGAN | System / Organ Class Affected by Second Adverse Event | Which system / organ classes were affected by the second adverse event? List each system / organ class, separated by a comma, using the list provided with this dictionary. | Char | | |
| AE2_OUTCOME | Outcome of Second Adverse Event | What was the outcome of the second adverse event? | Category | Recov | Recovered |
| | | | | NoRecov | Not Recovered |
| | | | | Died | Died |
| | | | | U | Unknown |
| AE3 | Third Adverse Event | Did the patient experience a serious adverse event and/or permanently stop the drug | Category | SAE | Serious Adverse Event |
| | | | | Perm | Permanent Stop |
| | | | | Both | Both |
| AE3_DATE | Date of Third Adverse event | What was the date of the permanent discontinuation of the drug(s)? | Date | | |
| AE3_DRUG | Drug Responsible for Third Adverse Event | List each drug, separated by a comma, using the provided abbreviations with this dictionary. | Char | | |
| AE3_GRADE | Grade of Third Adverse Event | What was the grade of the third adverse event? | Num ### | | |
| AE3_SYSTEMORGAN | System / Organ Class Affected by Third Adverse Event | Which system / organ classes were affected by the third adverse event? List each system / organ class, separated by a comma, using the list provided with this dictionary. | Char | | |
| AE3_OUTCOME | Outcome of Third Adverse Event | What was the outcome of the third adverse event? | Category | Recov | Recovered |
| | | | | NoRecov | Not Recovered |
| | | | | Died | Died |
| | | | | U | Unknown |
| *Additional adverse event entries can be entered following the same format. | | | | | |

| Follow-Up Culture Results* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| CULTURE_MONTH1 | Culture Result Month 1 | What is the culture result for the sputum sample tested during month 1? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH2 | Culture Result Month 2 | What is the culture result for the sputum sample tested during month 2? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH3 | Culture Result Month 3 | What is the culture result for the sputum sample tested during month 3? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH4 | Culture Result Month 4 | What is the culture result for the sputum sample tested during month 4? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH5 | Culture Result Month 5 | What is the culture result for the sputum sample tested during month 5? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH6 | Culture Result Month 6 | What is the culture result for the sputum sample tested during month 6? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH7 | Culture Result Month 7 | What is the culture result for the sputum sample tested during month 7? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH8 | Culture Result Month 8 | What is the culture result for the sputum sample tested during month 8? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH9 | Culture Result Month 9 | What is the culture result for the sputum sample tested during month 9? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH10 | Culture Result Month 10 | What is the culture result for the sputum sample tested during month 10? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH11 | Culture Result Month 11 | What is the culture result for the sputum sample tested during month 11? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH12 | Culture Result Month 12 | What is the culture result for the sputum sample tested during month 12? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH13 | Culture Result Month 13 | What is the culture result for the sputum sample tested during month 13? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH14 | Culture Result Month 14 | What is the culture result for the sputum sample tested during month 14? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH15 | Culture Result Month 15 | What is the culture result for the sputum sample tested during month 15? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH16 | Culture Result Month 16 | What is the culture result for the sputum sample tested during month 16? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |

| Follow-Up Culture Results* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| | | | | ND | Not Done |
| CULTURE_MONTH17 | Culture Result Month 17 | What is the culture result for the sputum sample tested during month 17? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH18 | Culture Result Month 18 | What is the culture result for the sputum sample tested during month 18? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH19 | Culture Result Month 19 | What is the culture result for the sputum sample tested during month 19? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH20 | Culture Result Month 20 | What is the culture result for the sputum sample tested during month 20? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH21 | Culture Result Month 21 | What is the culture result for the sputum sample tested during month 21? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH22 | Culture Result Month 22 | What is the culture result for the sputum sample tested during month 22? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH23 | Culture Result Month 23 | What is the culture result for the sputum sample tested during month 23? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| CULTURE_MONTH24 | Culture Result Month 24 | What is the culture result for the sputum sample tested during month 24? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |

*Month 1 refers to the result of the sample taken between day 31 and 60 that is closest to day 31 and valid (i.e., Positive or Negative); Month 2 refers to the sample taken between day 61 and 90 that is closest to day 61 and valid (i.e., Positive or Negative); the remaining months follow the same pattern. Any MTB colonies seen should be considered positive. If multiple samples are taken on a given day, a positive-dominant approach should be taken, whereby a patient is positive if a single positive sample is found. A patient sample should only be classified as contaminated if all samples from that month were contaminated.

| Follow-Up Smear Microscopy Results* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| SMEAR_MONTH1 | Smear Result Month 1 | What is the smear result for the sputum sample tested during month 1? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH2 | Smear Result Month 2 | What is the smear result for the sputum sample tested during month 2? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH3 | Smear Result Month 3 | What is the smear result for the sputum sample tested during month 3? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH4 | Smear Result Month 4 | What is the smear result for the sputum sample tested during month 4? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH5 | Smear Result Month 5 | What is the smear result for the sputum sample tested during month 5? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH6 | Smear Result Month 6 | What is the smear result for the sputum sample tested during month 6? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH7 | Smear Result Month 7 | What is the smear result for the sputum sample tested during month 7? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH8 | Smear Result Month 8 | What is the smear result for the sputum sample tested during month 8? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH9 | Smear Result Month 9 | What is the smear result for the sputum sample tested during month 9? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH10 | Smear Result Month 10 | What is the smear result for the sputum sample tested during month 10? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH11 | Smear Result Month 11 | What is the smear result for the sputum sample tested during month 11? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH12 | Smear Result Month 12 | What is the smear result for the sputum sample tested during month 12? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH13 | Smear Result Month 13 | What is the smear result for the sputum sample tested during month 13? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH14 | Smear Result Month 14 | What is the smear result for the sputum sample tested during month 14? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH15 | Smear Result Month 15 | What is the smear result for the sputum sample tested during month 15? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH16 | Smear Result Month 16 | | Category | Pos | Positive |
| | | | | Neg | Negative |

| Follow-Up Smear Microscopy Results* | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| | | What is the smear result for the sputum sample tested during month 16? | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH17 | Smear Result Month 17 | What is the smear result for the sputum sample tested during month 17? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH18 | Smear Result Month 18 | What is the smear result for the sputum sample tested during month 18? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH19 | Smear Result Month 19 | What is the smear result for the sputum sample tested during month 19? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH20 | Smear Result Month 20 | What is the smear result for the sputum sample tested during month 20? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH21 | Smear Result Month 21 | What is the smear result for the sputum sample tested during month 21? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH22 | Smear Result Month 22 | What is the smear result for the sputum sample tested during month 22? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH23 | Smear Result Month 23 | What is the smear result for the sputum sample tested during month 23? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |
| SMEAR_MONTH24 | Smear Result Month 24 | What is the smear result for the sputum sample tested during month 24? | Category | Pos | Positive |
| | | | | Neg | Negative |
| | | | | Contam | Contaminated |
| | | | | ND | Not Done |

*Any acid-fast bacilli seen should be considered positive. Month 1 refers to the result of the sample taken between day 31 and 60 that is closest to day 31 and valid (i.e., Positive or Negative); Month 2 refers to the sample taken between day 61 and 90 that is closest to day 61 and valid (i.e., Positive or Negative); the remaining months follow the same pattern. If multiple samples are taken within a given day, a positive-dominant approach should be taken, whereby a patient is positive if a single positive sample is found. A patient sample should be classified as contaminated only if all samples from that month were contaminated.

| Treatment Outcome Information | | | | | |
|---|---|---|---|---|---|
| **Field** | **Variable** | **Additional Information** | **Format** | **Category Coding** | **Category Labeling** |
| OUTCOME_DEFINITION | End-of-Treatment Outcome Definition | Specify the guideline year the outcome definition follows—this is preferably the 2013 guidelines but can follow 2005 guidelines if not available. | Category | WHO2013 | 2013 Definitions |
| | | | | WHO2005 | 2005 Definitions |
| OUTCOME | End-of-Treatment Outcome | End of treatment outcome assigned to the patient, following the outcome year specified above. | Category | Cure | Cure |
| | | | | Complete | Treatment Complete |
| | | | | Fail | Treatment Failure |
| | | | | Death | Death |
| | | | | LTFU | Loss to Follow-Up |
| CULTURECONV* | Culture Conversion | Did the patient culture convert (defined as two consecutive negative cultures taken at least 28 d apart)? If the patient was culture negative at baseline, list as BaseNeg. | Category | Y | Yes |
| | | | | N | No |
| | | | | BaseNeg | Baseline Negative |
| CULTURECONV_DATE | Date of Culture Conversion | If the patient culture converted, what was the date of conversion (defined as the date of the first of the two consecutive negative cultures)? | Date | | |
| TWOCONV | Culture Conversion by Month Two | If exact date of conversion is unknown, did culture conversion occur before the end of month two? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| SIXCONV | Culture Conversion by Month Six | If exact date of conversion is unknown, did culture conversion occur before the end of month six? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| CULTUREREV* | Culture Reversion | If patient converted or was culture negative at baseline, was there culture reversion (defined as two consecutive positive cultures taken at least 28 d apart)? | Category | Y | Yes |
| | | | | N | No |
| | | | | U | Unknown |
| CULTUREREV_DATE | Date of Culture Reversion | If patient had culture reversion, what was the date of reversion (defined as the date of the first of the two consecutive positive cultures)? | Date | | |
| RECURRENCE_MONITORING | Post-Treatment Recurrence Monitoring | Was post-treatment monitoring for recurrence performed? | Category | Y | Yes |
| | | | | N | No |
| RECURRENCE_FOLLOWUP_DUR | Duration of Recurrence Monitoring | What was the duration of recurrence monitoring, in months? | Num ### | | |
| RECURRENCE_OUTCOME | Occurrence of Recurrence | Did the patient experience recurrence? | Category | Y | Yes |
| | | | | N | No |
| RECURRENCE_DATE | Date of Recurrence | What was the date of the recurrence episode? | Date | | |
| RELAPSE_REINFECT | Relapse or Reinfection | If resources permitted, was the recurrence classified as a true relapse or as a reinfection? | Category | Relapse | Relapse |
| | | | | Reinfect | Reinfection |
| | | | | U | Unknown |
| *These can be reported by the individual providing data or calculated by an analyst. In the instance of multiple cultures taken at the same time, a positive dominant approach should be taken, i.e., the result should be considered positive if any of the samples are positive. In the case of contaminated results, these should be discarded when calculating time to culture conversion or reversion. | | | | | |

## Drug Abbreviations, System/Organ Classes, and End-of-Treatment Outcome Definitions

The tables contained within this section are intended to promote standardization in coding of drugs, outcomes, and adverse events.

| Tuberculosis Drug Name / Drug Class | Abbreviation |
|---|---|
| Isoniazid | H |
| Rifampin | R |
| Ethambutol | E |
| Pyrazinamide | Z |
| High Dose Isoniazid | HighH |
| Streptomycin | S |
| Rifabutin | Rfb |
| Amikacin | Am |
| Capreomycin | Cm |
| Kanamycin | Km |
| Ofloxacin | Ofx |
| Ciprofloxacin | Cfx |
| Moxifloxacin | Mfx |
| Levofloxacin | Lfx |
| Gatifloxacin | Gfx |
| Sparfloxacin | Sfx |
| Ethionamide | Eto |
| Prothionamide | Pto |
| Cycloserine | Cs |
| Terizidone | Trd |
| Para-Aminosalicylic Acid | PAS |
| Linezolid | Lzd |
| Clofazimine | Cfz |
| Amoxicillin and Clavulanic Acid | AmxClv |
| Imipenem-Cilastatin | Ipm |
| Meropenem | Mpm |
| Bedaquiline | Bdq |
| Delamanid | Dlm |
| Pretomanid | Pa |
| Perchlozone | Pcz |
| Thioacetazone | T |
| Rifapentine | Rpt |
| Second Line Injectables | SLI |
| Fluoroquinolones | FQ |

| Drug Name / Drug Class of Antiretroviral Therapy | Abbreviation |
|---|---|
| Nucleoside/Nucleotide Reverse transcription Inhibitor | NRTI |
| Abacavir | ABC |
| Didanosine | ddl |
| Emtricitabine | FTC |
| Lamivudine | 3TC |
| Stavudine | d4T |
| Tenofovir alafenamide | TAF |
| Tenofovir disoproxil fumarate | TDF |
| Zidovudine | AZT or ZDV |
| Non-nucleoside Reverse transcription Inhibitor | NNRTI |
| Delaviridine | DLV |
| Efavirenz | EFV |
| Etavirine | ETR |
| Nevirapine | NVP |
| Rilpivirine | RPV |
| Protease Inhibitor | PI |
| Amprenavir | AMV |
| Atazanavir | ATV |
| Darunavir | DRV |
| Fosamprenavir | FPV |
| Indinavir | IDV |
| Lopinavir + ritonavir | LPV/r |
| Nelfinavir | NFV |
| Saquinavir | SQV |
| Tipranavir | TPV |
| Fusion Inhibitor | FI |
| Enfuviritide | ENF or T-20 |
| CCR5 Antagonist | CCR5 |
| Maraviroc | MVC |
| Integrase Inhibitor | II |
| Bictegravir | BIC |
| Dolutegravir | DTG |
| Elvitegravir | EVG |
| Raltegravir | RAL |

| SYSTEM/ORGAN CLASS |
|---|
| Blood and lymphatic system disorders |
| Cardiac disorders |
| Congenital, familial and genetic disorders |
| Ear and labyrinth disorders |
| Endocrine disorders |
| Eye disorders |
| Gastrointestinal disorders |
| General disorders and administration site conditions |
| Hepatobiliary disorders |
| Immune system disorders |
| Infections and infestations |
| Injury, poisoning and procedural complications |
| Investigations |
| Metabolism and nutrition disorders |
| Musculoskeletal and connective tissue disorders |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |
| Nervous system disorders |
| Pregnancy, puerperium and perinatal conditions |
| Psychiatric disorders |
| Renal and urinary disorders |
| Reproductive system and breast disorders |
| Respiratory, thoracic and mediastinal disorders |
| Skin and subcutaneous tissue disorders |
| Social circumstances |
| Surgical and medical procedures |
| Vascular disorders |

| WHO 2013 Outcome Definitions (Preferred) | |
|---|---|
| **Outcome** | **Definition** |
| Cure | Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 d apart are negative after the intensive phase (or Month 8 if no intensive phase). |
| Complete | Treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 d apart are negative after the intensive phase (or Month 8 if no intensive phase). |
| Failure* | Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of: (1) lack of conversion by the end of the intensive phase, or (2) bacteriological reversion in the continuation phase after conversion to negative, or (3) evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, or (4) adverse drug reactions. |
| Death | 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. |

| WHO 2005 (Laserson) Outcome Definitions (if 2013 not possible) | |
|---|---|
| **Outcome** | **Definition** |
| Cure | Completed treatment according to program protocol and has at least five consecutive negative cultures from samples collected at least 30 d apart in the final 12 mo of treatment. If only one positive culture is reported during that time, and there is no concomitant clinical evidence of deterioration, a patient may still be considered cured, provided that this positive culture is followed by a minimum of three consecutive negative cultures taken at least 30 d apart. |
| Complete | Completed treatment according to program protocol but does not meet the definition for cure because of lack of bacteriological results (i.e., fewer than five cultures were performed in the final 12 mo of treatment). |
| Failure | Treatment will be considered to have failed if two or more of the five cultures recorded in the final 12 mo of therapy are positive, or if any one of the final three cultures is positive. (Treatment will also be considered to have failed if a clinical decision has been made to terminate treatment early because of poor clinical or radiological response or adverse events). |
| Death | A patient who dies for any reason during the course of MDR/RR-TB treatment |
| Lost to Follow-up | A patient whose treatment was interrupted for two or more consecutive months for any reason without medical approval. |

## Example of an Initial Data Sharing Agreement (Can Be Modified on a Case-By-Case Basis)

### LETTER OF AGREEMENT for IPD in MDR/RR TB

This letter of agreement is between the McGill University group (hereafter referred to as the McGill group) for an Individual Patient Data (IPD) meta-analysis in multidrug-resistant tuberculosis TB (MDR-TB), and [INSERT NAME OF INVESTIGATOR AND INSTITUTION] (hereafter referred to as the investigator), regarding the transfer and use of data collected by the investigator. The McGill group and the investigator agree to collaborate on [INSERT NAME OF PROJECT] according to the terms in this letter and those set out in the full project protocol, which is attached as Annex 1.

The McGill group agrees to:

- Obtain approval from the Research Ethics Board of the Montreal Chest Institute, McGill University Health Center for this research.
- Respect the confidentiality of all data received. They will not attempt to identify patients, nor contact patients directly.
- Respect the principle that the investigator continues to 'own' the data sent for inclusion in this analysis. When the data set is "cleaned" and preliminary analyses completed, a copy of the data set will be returned to the investigator.
- Perform data analysis that addresses the objectives specified in the attached study protocol only. Any additional analysis will be performed only after it has been approved by the investigator. For additional analyses that are closely related to these objectives, the investigator will be informed; approval will be assumed if the investigator does not reply within a specified interval. If the investigator has concerns or objections to any new analyses, these will be addressed and resolved before proceeding. Analyses to address completely novel objectives that have not been foreseen in the current study protocol must be actively approved by the investigator before these analyses are undertaken.
- Finish analyses and return the data to the investigator by the sunset date. This date will be the date by which the analyses must be completed, and any manuscript(s)

prepared. The tentative sunset date to complete analyses, and prepare related manuscripts is [INSERT DATE]. If a manuscript is submitted, the data must be held until peer review is completed, and then up to 1 year after publication – to allow time for responses to the findings (e.g., letters to the editor). However, after the sunset date no further new analysis can begin without agreement to the extension of the sunset date by the investigator.

• Share results of analyses with the investigator, and all members of the IPD group at intervals described in the study protocol.

• Prepare draft and final reports of results for the project and prepare manuscript(s) of results for publication. All draft reports and manuscripts will be reviewed and approved by the investigator, and all members of the IPD group before submission. The authorship of these reports will be "The Collaborative Group for Meta-Analysis of Updated Individual Patient Data in MDR-TB", followed by a listing of all members – in alphabetic order. The corresponding author will be Dr. Menzies of McGill.

The investigator agrees to:

• Verify whether they require approval from their local Research Ethics Board, depending on their institution's policy. If so, the investigator will obtain this approval before sending the data to the McGill group. No additional data will be collected from the patients, thus investigator will not need to obtain patients' consent for this analysis.

• Transfer a data file of information on all patients who were members of a cohort of MDR-TB patients which the investigator reported in earlier publications. This patient dataset will be rendered completely anonymous before forwarding this to the Montreal Chest Institute by removing all personal identifiers.

• Become a member of The Collaborative Group for Meta-Analysis of Updated Individual Patient Data in MDR-TB. This Collaborative Group will review all preliminary and final results of analyses performed by the McGill group, as well

as all reports of results – for the guideline groups, for public presentation, and for publication.

• Treat these preliminary results confidentially. The investigator will not publish (including posting on the Internet), present in any public forum, nor disseminate through any media these results without approval from the McGill Group and other members of the IPD Collaborative Group.

| | |
|---|---|
| Dr. Dick Menzies (for the McGill University Group) | Date |
| [Insert name and institution] | Date |