

Data Fields for IPD data set

Data dictionary for MDR/RR-TB IPD

FACILITY INFORMATION					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
COUNTRY	Country	Country of the primary source of data	Char		
TREATING_SITE	Treating Site Name	Name of the treating site (hospital or clinic) for the primary source of data	Char		
SITE_ID	Treating Site Identifier	Site ID number	Char		

PATIENT IDENTIFIER AND DEMOGRAPHICS					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
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 (<u>If Date of Birth is not available</u>)	Num ###		
DOB	Date of Birth	Date of the patients birth	Num ###		
SEX	Sex	Patient's biological sex at birth	Category	F	Female
				M	Male
				U	Unknown
WEIGHT	Weight	Patient's weight in kilograms at treatment start	Num ###		
HEIGHT	Height	Patient's height in centimetres	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 Labelling
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	Insulin-Dependent Diabetes Mellitus	Is the patient insulin dependent (if having diabetes)?	Category	Y	Yes
				N	No
				U	Unknown
HBA1C	Haemoglobin A1c Level	Patients HbA1c measure defined in percent (%) at treatment start	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 they were diagnosed	Num ###		
CD4	CD4 Count	If the patient is HIV-positive, what is their CD4 count at treatment start (cells/ μ L)?	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 an antiretroviral treatment, what year did they start?	Num ###		
ART_REGIMEN	Antiretroviral Treatment Regimen	What is the antiretroviral treatment regimen? 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 Labelling
PASTTX	Previous Treatment	Has the patient ever received tuberculosis treatment for >30 days?	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 days?	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 days?	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 Complete Fail Lost U	Cure Completed Treatment Treatment Failure Lost to Follow-up Unknown

DISEASE CHARACTERISTICS					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
DISEASE_SITE	Site of Tuberculosis Disease	The site of tuberculosis disease diagnosed in the patient	Category	PTB EPTB Both	
EXTRAPULM_SITE	Primary Site of Extrapulmonary Tuberculosis	If extrapulmonary tuberculosis is diagnosed, the primary site affected	Category	Miliary Genital CNS Periton Pericar Lymph Pleural GI Bone Joint Other	Miliary TB Genitourinary TB Central Nervous System TB TB Peritonitis TB Pericarditis TB Lymphadenitis Pleural TB Gastrointestinal TB Bone TB Joint TB Other
CAVITATION_BASE	Lung Cavitation	Was there presence of lung cavitation on chest x-ray at treatment start?	Category	Y N U	Yes No Unknown
BILATERAL_BASE	Bilateral Disease	Was there presence of bilateral disease on chest x-ray at treatment start?	Category	Y N U	Yes No Unknown
AFB_BASE			Category	Pos	Positive

	Acid-Fast Bacilli Smear Result	What was the patient's acid-fast bacilli smear result (taken up to 1 month after treatment start)? Consider all samples taken over this time frame and consider positive if any were positive (i.e. scanty or greater).		Neg	Negative
				Contam	Contaminated
				ND	Not Done
CULTURE_BASE	Sputum Culture Result	What was the patient's sputum culture result (take up to 1 month 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

GENOTYPIC DST					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
XPRT_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		
XPRT_RIFRESULT_BASE	Gene Xpert Rifampicin Resistance Result	What was the result for rifampicin 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_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 Rifampicin Resistance Result	What was the result for rifampicin 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_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

PHENOTYPIC DST					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
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 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 >2 µg/ml) on phenotypic DST?	Category	R	Resistant
				S	Susceptible
				Contam	Contaminated
				ND	Not Done
DST_R_BASE	Rifampicin Resistance Result	What was the result for rifampicin 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			Category	R	Resistant

	Pyrazinamide Resistance Result	What was the result for pyrazinamide resistance on phenotypic DST?		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_ETOPTO_BASE	Ethionamide / Prothionamide Resistance Result	What was the result for ethionamide / prothionamide resistance on phenotypic DST?	Category	R	Resistant
				S	Susceptible
				Contam	Contaminated

				ND	Not Done
DST_CSTRD_BASE	Cycloserine / Terizidone Resistance Result	What was the result for cycloserine / 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

FOLLOW-UP DST AND ACQUIRED DRUG RESISTANCE					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
FOLLOWUP_DST	Follow-up DST Performed	Was there follow-up DST performed?	Category	Y N	Yes 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. If none discovered, list “no change in DST.” 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. If none discovered, list “no change in DST.” 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). List each drug, separated by a comma, using the provided abbreviations with this dictionary.	Char		

REGIMEN INFORMATION					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
STARTINGREGIMENTYPE	Regimen Type at Start of Treatment	List the starting regimen type: short (intended duration 9-11 months) or long (intended duration ≥ 18 months)	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		
TWOMONTH_REGIMEN	Treatment Regimen at Month Two	List the drugs the patient is on at month two of treatment. List each drug, separated by a comma, using the provided abbreviations with this dictionary.	Char		
SIXMONTH_REGIMEN	Treatment Regimen at Month Six	List the drugs the patient is on at month six of treatment. List each drug, separated by a comma, using the provided abbreviations with this dictionary.	Char		
TWELVEMONTH_REGIMEN	Treatment Regimen at Month Twelve	List the drugs the patient is on at month twelve of treatment. List each drug, separated by a comma, using the provided abbreviations with this dictionary.	Char		
EIGHTEENMONTH_REGIMEN	Treatment Regimen at Month Eighteen	List the drugs the patient is on at month eighteen of treatment.	Char		

		List each drug, separated by a comma, using the provided abbreviations with this dictionary.			
END_REGIMEN	Treatment Regimen at End of Treatment	List the drugs the patient is on at the end of treatment. List each drug, separated by a comma, using the provided abbreviations with this dictionary.	Char		
TXEND_DATE	Treatment End Date	Date treatment ended in this treatment episode <mm/dd/yy>	Date		
REGIMENDURATION_CHANGE	Intended Duration of Regimen Changed	If the patient started on a short regimen, did they switch to a long regimen?	Category	Y N	Yes No

TREATMENT INFORMATION					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
BDQ_DURATION	Bedaquiline Duration	If the patient received bedaquiline, the total number of days the patient received it.	Num ###		
DLM_DURATION	Delamanid Duration	If the patient received delamanid, the total number of days the patient received it.	Num ###		
PA_DURATION	Pretomanid Duration	If the patient received pretomanid, the total number of days the patient received it.	Num ###		
INJ_DURATION	Injectable Duration	If the patient received an injectable, the total number of days the patient received it.	Num ###		
LZD_DURATION	Linezolid duration	If the patient received Linezolid, the total number of days the patient received it.	Num ###		
LZD_DOSE	Linezolid Dose	If the patient received Linezolid, indicate the initial daily dose (in mg) and any changes in dosing	Num ###		
CFZ_DURATION	Clofazimine duration	If the patient received clofazimine, the total number of days the patient received it.	Num ###		
Cs_DURATION	Cycloserine duration	If the patient received cycloserine, the total number of days the patient received it.	Num ###		
Pto_DURATION	Protionamide	If the patient received Protionamide, the total number of days the patient received it.	Num ###		
Z_DURATION	Pyrazinamide	If the patient received Pyrazinamide, the total number of days the patient received it.	Num ###		
TXDUR_MONTHS	Treatment Duration		Num ###		

CLINICVISIT_FREQUENCY	Frequency of follow up clinic visits	What is the frequency of clinic visits (usually at an outpatient department) in number of days during follow up?	Num ###		
DOT	Directly Observed Therapy	Was directly observed therapy used?	Category	Y N	Yes No
DOT_TYPE	Type of Directly Observed Therapy	State the type of directly observed therapy used. Virtual includes methods such as video.	Category	Comm Hosp Pharm Virtual	Community Hospital Pharmacy Virtual
DOT_FREQUENCY	Frequency of DOT Visits	How many days per week is DOT provided to the patient (range 1-7 days)	Num ###		
TXSUPPORT_DIGITAL	Digital medication monitors	Was digital medication monitors used during treatment?	Category	Y N U	Yes No Unknown
TXSUPPORT_TRACERS	Tracers (i.e. SMS, phone calls, etc)	Was tracers used during treatment?	Category	Y N U	Yes No Unknown
TXSUPPORT_PSYCHOLOGICAL	Psychological support	Was patient psychological support used during treatment?	Category	Y N U	Yes No Unknown
TXSUPPORT_EDUCATION	Patient education	Was patient education used during treatment?	Category	Y N U	Yes No Unknown
TXSUPPORT_MATERIAL	Material support (money, food, transport vouchers etc)	Was any material support used during treatment?	Category	Y N U	Yes No Unknown

SURGERY AND HOSPITALIZATION INFORMATION					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
SURGERY	Lung Resection Surgery	Did the patient have lung resection surgery related to MDR/RR-TB?	Category	Y N U	Yes No Unknown
SURGTYPE	Type of Lung Resection Surgery	What was the type of lung resection surgery?		Lobe Pneu	Lobectomy 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 Labelling
AE	Adverse Event Occurred	Did the patient permanently stop a drug in response to an adverse event during treatment?	Category	Y	Yes
				N	No
				U	Unknown
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 the drugs permanently stopped in response to the 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		
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 the drugs permanently stopped in response to the 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		
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 the drugs permanently stopped in response to the 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		

FOLLOW-UP MICROBIOLOGY RESULTS					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
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_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_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_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
				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_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_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_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

TREATMENT OUTCOME INFORMATION					
Field	Variable	Additional Information	Format	Category Coding	Category Labelling
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
OUTCOME_DATA	Date of end of treatment outcome	Date of treatment outcome assigned to the patient	Date		
CULTURECONV	Culture Conversion	Did the patient culture convert (defined as two consecutive negative cultures taken at least 28	Category	Y	Yes
				N	No

		days apart)? If the patient was culture negative at baseline, list as BaseNeg.		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 days 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		
RELAPSE_MONITORING	Post-Treatment Relapse Monitoring	Was post-treatment monitoring for relapse performed?	Category	Y	Yes
				N	No
RELAPSE_FOLLOWUP_DUR	Duration of Relapse Monitoring	What was the duration of follow up of relapse, in months?	Num ###		
RELAPSE_OUTCOME	Occurrence of Relapse	Did the patient experience relapse?	Category	Y	Yes
				N	No
RELAPSE_DATE	Date of Relapse	What was the date of the relapse episode?	Date		
RELAPSE_REINFECTION	Relapse or Reinfection	If resources permitted, was this classified as a true relapse or as a reinfection?	Category	Relapse	Relapse
				Reinfect	Reinfection
				U	Unknown

Annex 2. Drug Abbreviations, System/Organ Classes, and End-of-Treatment Outcome Definitions

Tuberculosis Drug Name / Drug Class	Abbreviation
Isoniazid	H
Rifampicin	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 Transcriptase Inhibitor	NRTI
Abacavir	ABC
Didanosine	ddI
Emtricitabine	3TC
Stavudine	d4T
Tenofovir alafenamide	TAF
Tenofovir disoproxil fumarate	TDF
Zidovudine	AZT or ZDV
Non-nucleoside Reverse Transcriptase Inhibitor	NNRTI
Delavirdine	DLV
Efavirenz	EFV
Etravirine	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
Enfuvirtide	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	Nix and ZeNix (MITT are considered primary)
Cure	Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase (or Month 8 if no intensive phase).	Favourable in all
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 days apart are negative after the intensive phase (or Month 8 if no intensive phase).	Unfavourable in MITT and PP
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.	Unfavourable in ITT, MITT and PP
Death	A patient who dies for any reason during the course of treatment	Unfavourable in ITT, MITT and PP (not including accidents)
Lost to Follow-up	A patient whose treatment was interrupted for 2 consecutive months or more.	Unfavourable in ITT, MITT