THE UNITED REPUBLIC OF TANZANIA

Ministry of Health

National Tuberculosis and Leprosy Programme

DRUG RESISTANT TB (DR-TB) aDSM FORM

The information collected will be kept confidential
PATIENT INITIALS _____

Birth Date_____ Sex ___ (M/F) DR-TB Reg. No. _____
Hospital File No.: _____ Facility _____ Council_____
Treatment Month._____

PREGNANCY ☐ YES ☐ NO ☐ N/A ☐ HEIGHT (cm) ☐ WEIGHT (kg) ☐

SAE or AE of special interest	☐ SAE ☐ AE of special interest

Serious adverse event(s) information	**SAE1**	**SAE2**	**SAE3**
Adverse event term			
Description of Adverse event			
Event onset date ***(dd/mm/yyyy)***	____ / ____ / ____	____ / ____ / ____	____ / ____ / ____
Event end date ***(dd/mm/yyyy)***	____ / ____ / ____	____ / ____ / ____	____ / ____ / ____
Duration if <1 day ***(hrs/min)***	____ / ____ /	____ / ____ /	____ / ____ /

If SAE, serious ness category		☐	☐	☐
	Death	*In case of death:* Death date: ____ / _____ / _____ Autopsy: Yes ☐ No ☐	*In case of death:* *Death date:* ____ / _____ / _____ Autopsy: Yes ☐ No ☐	*In case of death:* *Death date:* ____ / _____ / _____ Autopsy: Yes ☐ No ☐
	Life-threatening	☐	☐	☐
	Hospitalization required / prolonged	Required ☐ Prolonged ☐	Required ☐ Prolonged ☐	Required ☐ Prolonged ☐
		Hospitalization dates: Admission: ____ / ____ / _____ Discharge: ___ / ____ / ____	*Hospitalization dates:* *Admission:* ____ / ____ / _____ *Discharge:* ___ / ____ / ____	*Hospitalization dates:* *Admission:* ____ / ____ / _____ *Discharge:* ___ / ____ / ____
	Persistent or significant disability / incapacity	☐	☐	☐
	Congenital anomaly / birth defect	☐	☐	☐
	Otherwise medically mportant	☐	☐	☐

Adverse event of Special Interest	**Adverse Events** ☐ CNS Toxicity ☐ Hypokalemia ☐ Optic nerve disorder ☐ Hepatotoxicity ☐ Hypothyroidism ☐ Lacticacidosis ☐ Pancreatitis ☐ Nephrotoxicity ☐ Prolonged QT interval ☐ Ototoxicity ☐ Myelosuppression ☐ Peripheral neuropathy ☐ Other _____

	SUSPECTED DR-TB DRUG						
Suspected drug name (Generic and Brand)	**Dose & route**	**Formulation**	**Frequency**	**Batch number and expiry date**	**Treatment start date (dd/mm/yyyy)**	**Treatment stop date (dd/mm/yyyy)**	**Continued**
					___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
					___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
					___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
					___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
					___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐

CONCOMITANT MEDICATIONS					
Drug name (Generic and Brand)	**Daily dose and route**	**Indication**	**Treatment start date (dd/mm/yyyy)**	**Treatment stop date (dd/mm/yyyy)**	**Continued**
			___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
			___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
			___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
			___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐
			___ / ____ / ____	___ / ____ / ____	Yes ☐ No ☐

ACTION TAKEN	OUTCOME OF SAE
☐ Medicine withdrawn ☐ Dose not changed ☐ Dose Increased New Dose:_____ New frequency: _____ Times/Week ☐ Dose reduced New Dose:_____ New frequency: _____ Times/Week ☐ Unknown	☐ Recovered / Resolved ☐ Recovering / Resolving ☐ Recovered with sequealae ☐ Not recovered / Not resolved ☐ Died ☐ Unknown

Relevant Tests			
Tests done?	No ☐	Yes ☐	*If yes, providedetails below* ☐ Don't know
Test	**Date *(dd/mm/yyyy)***	**Result (unit)**	**Reference range**
	____ / _____ / _____		
	____ / _____ / _____		
	____ / _____ / _____		
	____ / _____ / _____		
	____ / _____ / _____		

Reporter				
Name of reporter:	**Designation:**	**Date of event's awareness:** **ALL SAEs to be reported within 24 hrs of awareness** ____ /____ /_____	**Address:** **Email:** **Phone:**	**Date and signature:** ___ /___ / _____