THE UNITED REPUBLIC OF TANZANIA

TB 24

Ministry of Health
National Tuberculosis and Leprosy Programme

TPT (3HP & 3HR) aDSM FORM

The information collected will be kept confidential

PATIENT INITIALS _____

Birth Date_____ Sex ___ (M/F) CTC Reg. No. _____

Hospital File No.: _____ Location _____

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***)		____ / _____	____ / _____	____ / _____
	Death	☐	☐	☐

If SAE, seriousness category		*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 important	☐	☐	☐

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 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	☐ Recovered / Resolved ☐ Recovering / Resolving

☐ Dose Increased New Dose: _____ New frequency: ___ times/week ☐ Dose reduced New Dose: _____ New frequency: ___ times/week ☐ Unknown	☐ Recovered with sequalae ☐ Not recovered / Not resolved ☐Died ☐ Unknown

Relevant Tests			
Tests done? No ☐ Yes ☐*If yes, provide details 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:** ____ /____ / _____