THE UNITED REPUBLIC OF TANZANIA

TB 23

Ministry of Health
National Tuberculosis and Leprosy Programme

TPT (3HP & 3HP) aDSM CAUSALITY ASSESSMENT FORM

The information collected will be kept confidential

PATIENT INITIALS _____

Date of Birth: _____ /_____ /_____ Sex _____ (M/F)

CTC Reg. No. _____ Hospital File No.: _____

Location: _____

Serious Adverse Event Causality Assessment

Causality assessment	**SAE 1**	**SAE 2**	**SAE 3**
Serious Adverse Event			
1st most likely drug Drug name: _____ _____	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible
2nd most likely drug Drug name: _____ _____	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible
3rd most likely drug Drug name: _____	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely	☐ Not related ☐ Probable ☐ Doubtful ☐ very likely	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely

_____	☐ Possible	☐ Possible	☐ Possible
4th most likely drug **Drug name:** _____ _____	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible
5th most likely drug **Drug name:** _____ _____	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible	☐ Not related ☐ Probable ☐ Doubtful ☐ Very likely ☐ Possible
Other causal factors (incl. med history, procedure, etc.)			
Event description Provide a clear description of the sequence of events, diagnosis, relevant investigation results (ECG, CT scan, etc.), corrective treatments and evolution.			

Adverse Event of Special Interest causality assessment

Adverse Event of Special Interest	**Severity**	**Additional comments**
☐ CNS Toxicity	Mild ☐ Moderate ☐ Severe☐	
☐Optic nerve disorder	Mild ☐ Moderate ☐ Severe☐	
☐Hypothyroidism	Mild ☐ Moderate ☐ Severe☐	

☐ Pancreatitis	Mild ☐ Moderate ☐ Severe☐	
☐ Prolonged QT interval	Mild ☐ Moderate ☐ Severe☐	
☐ Myelosuppression	Mild ☐ Moderate ☐ Severe☐	
☐Hypokalemia	Mild ☐ Moderate ☐ Severe☐	
☐Hepatotoxicity	Mild ☐ Moderate ☐ Severe☐	
☐Lacticacidosis	Mild ☐ Moderate ☐ Severe☐	
☐ Nephrotoxicity	Mild ☐ Moderate ☐ Severe☐	
☐ Ototoxicity	Mild ☐ Moderate ☐ Severe☐	
☐ Peripheral neuropathy	Mild ☐ Moderate ☐ Severe☐	
☐ Other _____	Mild ☐ Moderate ☐ Severe☐	

Date of PV meeting: **____ /____ / _____**	**Name of reporter:**	**Designation:**	**Address:** **Email:** **Phone:**	**Date and signature:** **____ /____ / _____**

OTHER COMMENTS:

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