Government of Nepal
Health Management Information System

aDSM Adverse Event Recording/Reporting Form

A. Patient and Health Facility Information

Name/Patient ID number (as DRTB Register:			Treatment Centre:	
Date of Birth (*or* Age):			Province:	
Sex:	☐ Male	☐ Female		
HIV status:	☐ Non-reactive	☐ Reactive		
Pregnancy:	☐ No	☐ Yes	Trimester:	
Weight (kg):			Height (cm):	BMI:

B. Adverse events experienced by patient (including abnormal investigations)

Adverse event	Onset date	End date	Severity grade	Seriousness *	Outcome §

* Please select: ***D*** *died* ***LT*** *life threatening* ***HA*** *caused or prolonged hospital admission* ***PD*** *permanent disability* ***OS*** *other medically serious* ***CA*** *congenital abnormality* ***NS*** *not serious*

§ Please select: ***A*** *recovered* ***B*** *recovering* ***C*** *recovered with residual effects* ***D*** *died* ***E*** *not recovered* ***F*** *unknown*

Detailed description of adverse event(s):

Was treatment of adverse event required? ☐ No ☐ Yes (please specify):

C. Laboratory assessment: Results of tests and procedures

Test performed	Test date	Result	Unit	Reference range

D. Medicines: DR-TB Regimen and other concomitant medicines, vaccines, traditional / herbal medicines and dietary supplements

☑ *Tick if medicine suspected of causing adverse event*

Medicine	Dose	Frequency	Route	Start date	Stop date	Reason for use	Action taken †	Response ‡
☐								
☐								
☐								
☐								
☐								

† *Action taken in response to AE:* ***DW*** *drug withdrawn* ***DR*** *dose reduced* ***DI*** *dose increased* ***DNC*** *dose not changed* ***UK*** *unknown* ***NA*** *not applicable*

‡ *Response to action taken:* ***RA*** *recovered* ***NE*** *no effect on AE* ***FA*** *fatal AE* ***UN*** *unknown* ***NA*** *not applicable*

E. Re-challenge information

List any medicines that were restarted and indicate effect on adverse event

Medicine	adverse event recurred	adverse event did not recur	unknown
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

F. Other relevant information e.g. medical history, concurrent illnesses, smoking, alcohol use and Hospital Management

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G. Causality Assessment at Treatment Center Level

1. Certain 2. Probable 3. Possible 4. Unlikely 5. Unassessed 6. Un-assessable

Comments:

H. Final AE/SAE Summary

Adverse Events Description:

Event Start date

Event End date

Severity Grading

Event classified: 1. Serious 2. Not – Serious (Based on Annex 2)

Narrative / Additional information (Final Result):

G. Reporter Information

Name:			Phone number:	
Email:				
Occupation:	☐ Doctor	☐ Nurse	☐ Paramedics	☐ Other (please specify):
Signature:			Date	

Submit form to:

Email to: M&E Unit, NTC: aDSMNTC@gmail.com

NTC Use Only:

Date received by NTC:						
Causality assessment:	☐ Certain	☐ Probable	☐ Possible	☐ Unlikely	☐ Unassessed	☐ Un-assessable
Comment:						
Reported to DDA:	☐ No	☐ Yes		Date reported to DDA:		