Sample treatment initiation form – Active TB drug-safety monitoring and management (aDSM)

Interview date: dd/mmm/yyyy

PATIENT DETAILS

Patient Name: ..... Patient ID: ……..…

Date of birth: dd/mmm/yyyy Age: ..... Sex at birth ❑ male ❑ female

TREATMENT PROVIDER

District Health Facility & address

Clinician/ Team Patient File number

Interview site ❑ Health Centre ❑ Hospital Clinic ❑ Phone interview ❑ Home visit ❑ Other

MEDICAL DETAILS

Weight (kg) Height (cm)

Indication for treatment ❑ Pulmonary TB ❑ Extra-pulmonary TB ❑ TB site/s:…… ❑ MDR-TB ❑ Prophylaxis

Prior exposure to anti-TB medicines ❑ No ❑ Yes ❑ Unknown

Pregnant ❑ Yes Date of LMP: dd/mmm/yyyy or estimated current gestation (weeks):

❑ Uncertain If PREGNANT record patient details in PREGNANCY REGISTER for follow-up

❑ No

Breastfeeding an infant ❑ No ❑ Yes

Injecting Drug Use Within Past Year ❑ No ❑ Yes ❑ Unknown

Tobacco use within the past year ❑ No ❑ Yes ❑ Unknown

Excessive alcohol use in the past year ❑ No ❑ Yes ❑ Unknown

Documented HIV infection ❑ No ❑ Yes ❑ Unknown

CURRENT AND PAST MEDICAL CONDITIONS & EVENTS (List) +	Date of Onset	Date of recovery	Continues
			❑
			❑
			❑
			❑
			❑
			❑
			❑
			❑
			❑

+ If the treatment centre offers intermediate and advanced packages of aDSM, conditions in relation to adverse events of special interest need to be examined and included in the list

LABORATORY & OTHER TESTS.* Include laboratory tests taken at any time during the PAST 30 DAYS

Test	Date	Result (units)	Test	Date	Result (units)
Sputum smear			ESR		
Sputum culture			Total WBC		
Drug susceptibility**			Haemoglobin		
Line probe assay			ALT (SGPT)		
Nucleic acid testing			AST (SGOT)		
Tuberculin Test			Creatinine		
HIV Antibody			Creatinine Clearance		
CD4 Count			Glucose		
Chest X Ray		Cavities (Y/N)	Thyroid function (TSH)		
Audiometry			Electrocardiogram		QTc
Visual acuity			Other		
Hepatitis markers			Other		

* Additional tests may need to be included for adverse events of special interest if the treatment centre offers intermediate or advanced package for aDSM (See Instructions)
** DST to the following drugs may be useful to record on this form or elsewhere in an accessible electronic medical record: isoniazid, rifampicin, kanamycin (and/or amikacin), capreomycin, ofloxacin (or ciprofloxacin), levofloxacin and moxifloxacin.

MEDICINES							
Medicines & traditional medicines taken at any time in PAST 30 DAYS	**Indication**	**Dosage**	**Frequency**	**Route**	**Start date**	**Stop date**	**Continues**
							❑
							❑
							❑
							❑
							❑
							❑
							❑
							❑

All NEW Anti-TB medicines prescribed at this interview	**Indication**	**Dosage**	**Frequency**	**Route**	**Start date**	**Anticipated Stop date**
All other NEW medicines prescribed at this interview	**Indication**	**Dosage**	**Frequency**	**Route**	**Start date**	**Anticipated Stop date**

Name of the Reporter: .....

Please give this form to the aDSM Focal Person

Focal Person: ..... Phone: .....

Date of next appointment: dd/mmm/yyyy

Instructions for the completion of the TREATMENT INITIATION FORM

A **Treatment Initiation Form** should be completed at treatment initiation: the interview at which anti-tuberculosis therapy is commenced and at which the patient is enrolled in the aDSM programme. This form represents a template and the programme may wish to adapt it according to its needs and preferences; it includes all of the essential data elements to be collected for the aDSM as recommended by WHO.

Patient participation

It is important that monitoring begins at the commencement of therapy. Patients may be enrolled if they are beginning treatment with the monitored medicine(s) for the first time (i.e. treatment naïve) or if their regimen is being changed. Patients who have previously been exposed to anti-TB medicines may also be included in the cohort, but monitoring should begin at the commencement of a new course of treatment.

Patients should be informed about the purpose of the monitoring programme and their agreement to participate should be sought prior to enrolment. Patients who are unwilling to participate should not be enrolled in the monitoring programme.

Patient ID

Type of identification to be selected by country.

Tick boxes (✔)

Where there are tick boxes, please answer by placing a tick ✔ in the appropriate box.

Patient details

Patient initials

Please use initials of given name(s) and family name.

Date of birth

If DOB is unknown, record the patient's age (or estimated age, if true age is unknown).

Treatment provider

Patient file number

Record the file number used to identify the patient in your clinic.

Medical details

Weight & height

Record the patient's current weight and height on the date of interview.

Pregnant

If this patient is currently pregnant, please record her details in the **Pregnancy Register** to ensure outcome of pregnancy is followed up.

Indication for treatment

Please indicate whether the anti-tuberculosis therapy is to be used for the treatment of pulmonary TB, extra-pulmonary TB, MDR-TB or for prophylaxis. More than one box may be ticked.

CURRENT AND PAST MEDICAL CONDITIONS & EVENTS (List)

Indicate any significant concomitant diagnoses, past medical conditions and events. Include the onset date, if known, and either record the date of recovery or, if the condition is ongoing, note that it 'continues' (Record the approximate date if the exact date is unknown).

If the treatment centre offers intermediate and advanced packages of aDSM, conditions in relation to adverse events of special interest need to be examined and included in the list.

Adverse event of special interest is an adverse event documented to have occurred during clinical trials and for which the monitoring programme is specifically sensitized to report regardless of its seriousness, severity or causal relationship to the TB treatment. The centres which offer the intermediate and advanced packages of aDSM will include all adverse events of special interest in their reporting.

Adverse event of clinical significance is an adverse event which is either (i) serious, (ii) of special interest, (iii) leads to a discontinuation or change in the treatment, or (iv) is judged as otherwise clinically significant by the clinician. The centres which offer the advanced package of aDSM will include all adverse events of clinical significance in their reporting.

LABORATORY & OTHER TESTS

Record the results (including *units*) of any laboratory tests taken in the PAST 30 DAYS. Commonly performed tests have been listed; other tests may be recorded in the space provided. The list of tests is indicative but may be reduced or increased depending on the regimen used and resources.

If the treatment centre offers intermediate or advanced package for aDSM, additional tests may need to be included for adverse events of special interest.

MEDICINES

Medicines & traditional medicines taken at any time in PAST 30 DAYS

Record the details of any prescription or over-the counter medicines and any traditional medicines, herbal remedies or health supplements taken at any time during the PAST 30 DAYS. Include the *units* the '**Dosage**' column. If a medicine is given as a fixed dose combination (FDC), either as a co-formulation or in a co-blister pack, record the number of dosage forms (DF) given.

All new medicines prescribed at this interview

Please record the details of all medicines prescribed at this interview, for TB or non-TB in the separate Tables.

Sample treatment review form – aDSM

Interview date: dd/mmm/yyyy

PATIENT DETAILS

Patient Name: ..... Patient ID: ……..…..

Date of birth: dd/mmm/yyyy Age: ..... Sex at birth ❑ male ❑ female

TREATMENT PROVIDER

District Health Facility & address

Clinician/ Team Patient File number

Interview site ❑ Health Centre ❑ Hospital Clinic ❑ Phone interview ❑ Home visit ❑ Other

MEDICAL DETAILS

Weight (kg) Height (cm)

Indication for treatment ❑ Pulmonary TB ❑ Extra-pulmonary TB ❑ TB site/s:…… ❑ MDR-TB ❑ Prophylaxis

Prior exposure to anti-TB medicines ❑ No ❑ Yes ❑ Unknown

Pregnant ❑ Yes Date of LMP: dd/mmm/yyyy *or* estimated current gestation (weeks):

❑ Uncertain If PREGNANT record patient details in PREGNANCY REGISTER for follow-up

❑ No

Breastfeeding an infant ❑ No ❑ Yes

		Record all NEW EVENTS or CHANGES in pre-existing conditions since last interview					
Events*	**AE MedDRA / WHO-ART code****	**Date onset**	**Date resolved**	**Outcome*****	**Severity†**	**Seriousness‡**	**Rechallenge§**

* All PMDT sites treating eligible patients with new anti-TB drugs, novel regimens for MDR-TB or XDR-TB need to report at least all serious adverse events (SAEs) as required in the Core package. The centres which offer the advanced package of aDSM need to report all adverse events of clinical significance in their reporting. The centres which offer the intermediate and advanced packages of aDSM need to report all adverse events of special interest in their reporting. (See Instructions for more details)

** to be completed by PV centre after data collection (see also Instructions for completion)

***OUTCOME		MAXIMAL SEVERITY†		SERIOUSNESS‡		RECHALLENGE§	
R1	Recovered/ resolved	1	Mild	N	Not serious	1	No rechallenge
R2	Recovering/resolving	2	Moderate	H	Hospitalization (caused or prolonged)	2	Recurrence of event
S	Recovered with sequelae	3	Severe	P	Permanent disability	3	No recurrence
N	Not recovered/not resolved			C	Congenital abnormality	4	Result unknown
D	Died			L	Life threatening		
U	Unknown			D	Death		

Scale used for grading of severity of AEs :

❑ Clinician's judgement ❑ CTCAE grading system ❑ DAIDS AE Grading Table

❑ Other (specify): .....)

LABORATORY & OTHER TESTS*

Test	Date	Result (units)	Test	Date	Result (units)
HIV Antibody			ALT (SGPT)		
CD4 Count			AST (SGOT)		
ESR			Lactic acid		
Total WBC			Lipase		
Haemoglobin			Chest X-Ray		Cavities (Y/N)
Creatinine			ECG		QTc
Creatinine Clearance			Audiometry		
Glucose			Visual acuity		
Hepatitis markers			Other		
TSH			Other		

MEDICINES

Anti-TB medicines taken since last interview	Dosage	Frequency	Route	Start date	Stop date	Continues	Reason(s) for stopping #	Action**
						❑		
						❑		
						❑		
						❑		
						❑		
						❑		

Other medicines & traditional medicines taken since last interview	Dosage	Frequency	Route	Start date	Stop date	Continues	Reason(s) for stopping #	Action**
						❑		
						❑		
						❑		
						❑		
						❑		
						❑		
						❑		

* Additional tests may need to be included for monitoring of adverse events of special interest when the treatment centre offers intermediate or advanced package for aDSM (See Instructions)

REASON FOR STOPPING
1 Adverse event
2 Poor adherence
3 Course completed or cured*
4 Planned interruption
5 Planned medication change
6 No longer needed
7 Treatment failure*
8 Pregnancy
9 Drug out of stock
10 Cost
11 Patient decision
12 Died*
13 Lost to follow-up*
14 Other (please specify)

**ACTION TAKEN BY CLINICIAN IN CASE OF SUSPECTED ADVERSE EVENT LINKED TO A DRUG
Dose not changed
Drug withdrawn
Not applicable
Dose reduced
Drug interrupted

All NEW medicines (anti-TB & other) prescribed at this interview	Dosage	Frequency	Route	Start date	Expected stop date	Indication

Outcome* (to be completed at the end of current treatment episode)

❑ Cured	❑ Completed	❑ Treatment failed	❑ Died	❑ Loss to follow up	❑ Not evaluated

If the end of the treatment episode, treatment outcome date : dd/mmm/yyyy

* as per *Definitions and reporting framework for tuberculosis – 2013 revision (WHO/HTM/TB/2013.2). Geneva, World Health Organization; 2013. Available from: www.who.int/iris/bitstream/10665/79199/1/9789241505345_eng.pdf*

Name of the Reporter: .....

Please give this form to the aDSM Focal Person

Focal Person: ..... Phone: .....

Date of next appointment: dd/mmm/yyyy

Instructions for the completion of the TREATMENT REVIEW FORM

A **Treatment Review Form** should be completed each time the patient is interviewed following commencement of treatment with the monitored medicine(s). This form represents a template and the programme may wish to adapt it according to its needs and preferences; it includes all of the essential data elements to be collected for the aDSM as recommended by WHO.

Patient ID

Type of unique patient identification to be selected by country.

Tick boxes (✔)

Where there are tick boxes, please answer by placing a tick ✔ in the appropriate box.

PATIENT DETAILS

Patient initials

Please use initials of given name(s) and family name.

Date of birth

If DOB is unknown, record the patient's age (or estimated age, if true age is unknown)

TREATMENT PROVIDER

Patient file number

Record the file number used to identify this patient in your clinic

MEDICAL DETAILS

Weight & height

Record the patient's current weight on the date of follow-up visit. Height should be recorded for children at treatment review, but is unnecessary for adults.

Indication for treatment

Please indicate whether the anti-tuberculosis therapy is to be used for the treatment of pulmonary TB, extra-pulmonary TB, MDR TB or for prophylaxis. More than one box may be ticked.

Pregnant

Please indicate whether the patient is pregnant, uncertain or not pregnant. Women who are pregnant should be entered into a pregnancy register to ensure that the outcome of the pregnancy is followed-up.

EVENTS

Please record:

- All **new health events** that have occurred since the patient started the monitored medicine.
- This includes any **deterioration or improvement in pre-existing conditions** (or previously recorded events)-

- All PMDT sites treating eligible patients with new anti-TB drugs, novel regimens for MDR-TB or XDR-TB need to report at least all serious adverse events (SAEs) as required in the Core package.

- The centres which offer the advanced package of aDSM need to report all adverse events of clinical significance in their reporting. **Adverse event of clinical significance*** is an adverse event which is either (i) serious, (ii) of special interest, (iii) leads to a discontinuation or change in the treatment, or (iv) is judged as otherwise clinically significant by the clinician.

- The centres which offer the intermediate and advanced packages of aDSM need to report all adverse events of special interest in their reporting. **Adverse event of special interest*** is an adverse event documented to have occurred during clinical trials and for which the monitoring programme is specifically sensitized to report regardless of its seriousness, severity or causal relationship to the TB treatment.

For each event, select the appropriate code for **Outcome**, **Severity**, **Seriousness** and **Rechallenge** from the shaded panel**.** Choose Clinician's judgement if no scale is used to classify the severity of the event other than the health professional's opinion. If the severity coding used is not “Mild”, “Moderate”, “Severe” please adjust accordingly. Indicate the "Scale used for grading of severity of AEs".

Coding of the events (using AE MedDRA or WHO-ART code) is done by the expert in pharmacovigilance in consultation with the clinician in charge of the patient; it is not necessarily performed by the person completing the questionnaire. A record on the attribution of an event to one or more medications will be made in the database but is not included in the forms.

LABORATORY & OTHER TESTS

Record the results (including *units*) of any laboratory tests taken since the patient was last interviewed. Commonly performed tests have been listed; other tests may be recorded in the space provided. The list of tests is indicative but may be reduced or increased depending on the regimen used and resources.

MEDICINES

Anti-tuberculosis medicines or regimen taken since last interview
Anti-tuberculosis medicines may be recorded either as individual medicines or as fixed dose combinations (FDC). Include start and stop dates for medicines that were started or stopped during the interval since the patient was last interviewed and indicate which medicines continue to be taken (continues ✔). For medicines that have been stopped, please select the **reason(s) for stopping** from the list of codes provided (more than one code may be used). For Anti-tuberculosis medicines, please also select the appropriate **adherence code**. Note: If a medicine was stopped and later restarted, include separate entries for each course. If the dose was changed, record the medicine again on a new line with the new dose and dates.

Other medicines & traditional medicines taken since last interview
Record the details of other medicines, including over-the-counter medicines and any traditional medicines, herbal remedies or health supplements taken since the last interview.

All new medicines (Anti-tuberculosis & other) prescribed at this interview
Record the details of all new medicines (Anti-tuberculosis and other medicines) prescribed at this interview.