WHO Global Clinical Platform for Mpox
Data for public health response

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Global Clinical Data Platform

MONKEYPOX CASE REPORT FORM (CRF)

MODULE 4

INTRODUCTION

The CRF is designed to collect data obtained through examination, interview and review of hospital or clinic notes of patients with suspected, probable or confirmed monkeypox (mpox) infection. The CRF captures data from patients being managed in outpatient services or in community-based health services or during hospital admissions. Follow-up visits (Module 2) may be conducted in person or virtually as per local practice.

Data may be collected prospectively or retrospectively. The data collection period is defined as the period from hospital admission, or first clinic visit, to discharge from care, transfer, death or continued hospitalization without possibility of continued data collection.

This CRF has five modules:

Module 1:	To be completed on the first day of presentation or admission to the health centre (baseline visit).
Module 2:	To be completed on hospital days or follow-up visits (remote visits or visits to health centre) every 3–5 days and day 14.
Module 3:	To be completed at the last visit, either hospital discharge, transfer, last outpatient follow-up or death.
Module 4:	To be completed to record serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) for patients treated with tecovirimat under **WHO emergency use protocol for tecovirimat for monkeypox under MEURI framework.**
Module 5.1:	To be completed if currently pregnant or recently pregnant ≤ 21 days.
Module 5.2:	To be completed at end of pregnancy.

GENERAL GUIDANCE

Participant identification numbers consist of a site code and a participant number. You can register on the data management system by completing the mpox registration form, and our data management team will contact you with instructions for data entry and will assign you a five-digit site code at that time. Please contact us at monkeypox_clinicaldataplatform@who.int for any further information.

MODULE 4. Tecovirimat SAE/SUSAR form

To complete if patient is participating in WHO emergency use protocol for tecovirimat for monkeypox under MEURI framework and has experienced a serious adverse event (SAE) or suspected unexpected serious adverse reaction (SUSAR).

Instructions

For each SAE/SUSAR complete a separate Module 4 form.
If the event has multiple linked events, you can record on one Module 4 form.

Facility/clinic name _____ **Country** _____

Location of encounter:

☐ Outpatient service If outpatient service, please indicate: ☐Home visit ☐ Clinic visit ☐Virtual ☐ Telephone call

☐ Emergency department ☐ Inpatient ward ☐ Other, specify _____

Date this module was completed [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

Sex at birth ☐Male ☐Female ☐Intersex ☐Not specified

Date of birth [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is unknown, record Age [_][_][_] years OR [_][_] months OR [_][_] days

Height [___] [___][___]cm Weight [_][_][___]kg

Date of first dose of tecovirimat [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Date of last dose of tecovirimat [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Ongoing ☐

Dose [_ _][_ _][_ _]mg

Health care professional details	Name _____ Telephone number _____ E-mail address _____ Consent to be contacted ☐

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SAE/SUSAR report

Please list patient SAE/SUSAR, with date of onset, resolution (or check ongoing) and list outcome and causality using the WHO UMC assessment tool: https://who-umc.org/media/164200/who-umc-causality-assessment_new-logo.pdf

SAE/SUSAR (specify diagnosis if available)	Onset and resolution dates	Outcome	Relationship to tecovirimat
	Onset [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Resolution [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Ongoing ☐	☐ Recovered/resolved ☐ Recovering/resolving ☐ Not recovered/not resolved/ongoing ☐ Recovered/resolved with sequelae ☐ Fatal ☐ Unknown	☐ Certain ☐ Probable/likely ☐ Possible ☐ Unlikely ☐ Conditional/unclassified ☐ Unassessable/unclassifiable

 WHO reference number: WHO/MPX/Clinical_CRF/Module_4/2023.4

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Linked events (*leave blank if not linked and compete an additional Module 4 for each individual event*)

Linked event (specify diagnosis if available)	Onset and resolution dates	Outcome	Relationship to tecovirimat
	Onset [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Resolution [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Ongoing ☐	☐ Recovered/resolved ☐ Recovering/resolving ☐ Not recovered/not resolved/ongoing ☐ Recovered/resolved with sequelae ☐ Fatal ☐ Unknown	☐ Certain ☐ Probable/likely ☐ Possible ☐ Unlikely ☐ Conditional/unclassified ☐ Unassessable/unclassifiable
Seriousness criteria: Please select the seriousness of each event			
☐ Serious (includes fatal, life threatening, required inpatient hospitalization, prolonged hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, other medically significant event) ☐ Non-serious			
Linked event (specify diagnosis if available)	**Onset and resolution dates**	**Outcome**	**Relationship to tecovirimat**
	Onset [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Resolution [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Ongoing ☐	☐ Recovered/resolved ☐ Recovering/resolving ☐ Not recovered/not resolved/ongoing ☐ Recovered/resolved with sequelae ☐ Fatal ☐ Unknown	☐ Certain ☐ Probable/likely ☐ Possible ☐ Unlikely ☐ Conditional/unclassified ☐ Unassessable/unclassifiable
Seriousness criteria: Please select the seriousness of each event			
☐ Serious (includes fatal, life threatening, required inpatient hospitalization, prolonged hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, other medically significant event) ☐ Non-serious			

Did the patient require hospitalization for this SAE/SUSAR?

☐Yes ☐Patient was already admitted ☐No

If patient was hospitalized due to SAE/SUSAR event:

Date of admission [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Date of discharge [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Did the patient require a tecovirimat interruption or dosage modifications?

☐No change to dose or duration of tecovirimat

☐Temporarily stopped tecovirimat Date stopped [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Did event resolve or improve after interruption? ☐Yes ☐No ☐Unknown

Date restarted [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

☐Permanently stopped tecovirimat Date stopped: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Did event resolve or improve after tecovirimat was stopped? ☐Yes ☐No ☐Unknown

Any changes to tecovirimat dose, route or frequency? ☐Yes ☐No ☐Unknown

If yes, specify:_____

Patient death

If SAE/SUSAR resulted in death, date of death [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Was autopsy performed? ☐Yes ☐No ☐Unknown

If yes, provide copy of autopsy result (upload link available on RedCap)

Laboratory investigations performed due to SAE/SUSAR (*record the most significant abnormality and date performed*)

Investigation	**Units (if different from unit listed)**	**Result**	**Date of test**	
ALT (U/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
AST (U/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Creatinine (µmol/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Potassium (mEg/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Urea (mmol/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Creatinine kinase (U/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Glucose (mg/dL)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Lactate (mmol/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Haemoglobin (g/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Total bilirubin (mg/dL)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
WBC count (cells x 10^9/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Prothrombin time (secs)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Activated partial thromboplastin time (aPTT)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Platelets (x10^9/L)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
CRP (mg/dL)			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Other, specify			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Other, specify			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Other, specify			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Other, specify			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Other, specify			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done
Other, specify			[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	☐ Not done

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Did the patient receive any medications to manage SAE/SUSAR?

Note: Concomitant medications and medical conditions are both recorded in CRF Module 1.

Please document here any additional medications used to manage the SAE/SUSAR.

Generic name	Dose[a]	Route[b]	Frequency[c]	Date started	Date stopped
				[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] or ☐ Ongoing
				[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] or ☐ Ongoing
				[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] or ☐ Ongoing
				[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] or ☐ Ongoing
				[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] or ☐ Ongoing

[a] Milligram (mg), microgram (ug), millilitre (mL), gram (g), international units (IU) and other (specify dose).

[b] Oral (PO), intravenous (IV), intramuscular (IM), subcutaneous (SC), sublingual (SL), rectal (PR), transdermal (TD), inhalation (INH), ocular (OC), topical (TOP) and other (specify route).

[c] Once daily (OD), twice daily (BD), three times daily (TDS), four times daily (QDS), as required (PRN) and other (specify frequency).

SAE/SUSAR narrative

Please provide full details of the clinical course of the event or death