Global Clinical Data Platform

Monkeypox

CASE REPORT FORM (CRF)

INTRODUCTION

The Rapid Core 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 infection. 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 three modules:

Module 1:	To be completed on the first day of presentation or admission to the health centre.
Module 2:	To be completed daily during hospital stay for as many days as resources allow, or on follow-up visits to health centre.
Module 3:	To be completed at last visit, either hospital discharge or last follow-up.
Pregnancy module:	To be completed if currently pregnant or recently pregnant <=21 days.

GENERAL GUIDANCE

Participant identification numbers consist of a site code and a participant number. You can register on the data management system by monkeypox_clinicaldataplatform@who.int and our data management team will contact you with instructions for data entry and will assign you a 5-digit site code at that time.
Please contact us at monkeypox_clinicaldataplatform@who.int for any information.

MODULE 1. Complete on hospital admission (within 24 hrs from admission) or first visit to outpatients

Facility/clinic name _____ **Country** _____

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

1a. DEMOGRAPHICS

Sex at birth ☐Male ☐Female ☐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**
Health care worker? ☐Yes ☐No ☐Unknown **Laboratory worker?** ☐Yes ☐No ☐Unknown
If yes: ☐not wearing all recommended PPE ☐wearing all recommended PPE ☐other specify
Race/ethnicity (tick all that apply) ☐Asian ☐African/Black ☐Caucasian/White
☐Hispanic/Latino ☐Other ☐Unknown
History of smallpox vaccination ☐Yes ☐No ☐Unknown
History of tetanus vaccination ☐Yes ☐No ☐Unknown
Pregnant?* ☐Yes ☐No ☐Unknown ☐N/A **If yes: Gestational weeks assessment** [___][_] weeks
If No, was person recently pregnant: within ≤ 21 days? ☐Yes ☐No ☐Unknown.
If Yes, also complete Pregnancy Module

1b. DATE OF ONSET AND ADMISSION VITAL SIGNS *(first available data at presentation/admission)*

Symptom onset (date of first/earliest symptom) [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

First described symptom/s:_____
_____
_____

Admission or visit date at this facility
[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **Temperature** [_][_____].[_
]°C

Heart rate [___][___][_]beats/min **Respiratory rate** [_][___]breaths/min
BP [_] [_] [_](systolic) [___][_][_](diastolic) mmHg **Severe dehydration** ☐Yes ☐No ☐Unknown

Alert Voice Pain Unresponsive (circle one)

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

1c. CO-MORBIDITIES *(existing at admission or initial visit)*

Chronic cardiac disease (not hypertension)	☐Yes	☐No	☐Unknown	Diabetes	☐Yes	☐No	☐Unknown
Hypertension	☐Yes	☐No	☐Unknown	Current smoking	☐Yes	☐No	☐Unknown
Chronic pulmonary disease	☐Yes	☐No	☐Unknown	Tuberculosis (*active*)	☐Yes	☐No	☐Unknown
Asthma	☐Yes	☐No	☐Unknown	Tuberculosis (*previous*)	☐Yes	☐No	☐Unknown
Chronic kidney disease	☐Yes	☐No	☐Unknown	Asplenia	☐Yes	☐No	☐Unknown
Chronic liver disease	☐Yes	☐No	☐Unknown	Malignant neoplasm	☐Yes	☐No	☐Unknown
Chronic neurological disorder	☐Yes	☐No	☐Unknown	If yes, on therapy for neoplasm at present?	☐Yes	☐No	☐Unknown
Current alcohol use	☐Yes	☐No	☐Unknown	On immunosuppressants	☐Yes	☐No	☐Unknown
Known current sexually transmitted infection	☐Yes	☐No	☐Unknown	If yes, specify _____			
				Immunosuppressive condition	☐Yes	☐No	☐Unknown
If yes, specify: _____				If yes, specify: _____			

HIV ☐Yes (on ART) ☐Yes (not on ART) ☐No ☐Unknown
ART regimen_____
Most recent CD4: [ ][ ][ ]

1d. SIGNS AND SYMPTOMS ON ADMISSION

Number of lesions on the entire body that are NOT resolved (resolved = scabbed and desquamated):

☐0 ☐1–5 ☐6–25 ☐26–100 ☐> 100 ☐> 250

Number of lesions on the right leg (to the hip crease, including front and back of foot and leg): [__][__][__][__]

Number of lesions on the right arm (including hand and shoulder): [__][__][__][__]

Number of lesions on the left leg (to the hip crease, including front and back of foot and leg): [__][__][__][__]

Number of lesions on the left arm (including hand and shoulder): [__][__][__][__]

Number of lesions on the genitals (from hip crease to hip crease): [__][__][__][__]

Does the patient have active lesions in the following areas:

Face	☐Yes	☐No	☐Unknown	Palms of hands	☐Yes	☐No	☐Unknown
Nose	☐Yes	☐No	☐Unknown	Arms	☐Yes	☐No	☐Unknown
Mouth	☐Yes	☐No	☐Unknown	Forearms	☐Yes	☐No	☐Unknown
Chest	☐Yes	☐No	☐Unknown	Thighs	☐Yes	☐No	☐Unknown
Abdomen	☐Yes	☐No	☐Unknown	Legs	☐Yes	☐No	☐Unknown
Back	☐Yes	☐No	☐Unknown	Soles of feet	☐Yes	☐No	☐Unknown
Perianal	☐Yes	☐No	☐Unknown	Other	☐Yes	☐No	☐Unknown
Genitals	☐Yes	☐No	☐Unknown	Specify where:	_____		

Types of lesions on the body:

Macule	☐Yes	☐No	☐Unknown	Umbilicated pustule	☐Yes	☐No	☐Unknown
Papule	☐Yes	☐No	☐Unknown	Ulcerated lesion	☐Yes	☐No	☐Unknown
Early vesicle	☐Yes	☐No	☐Unknown	Crusting of a mature lesion	☐Yes	☐No	☐Unknown
Small pustule	☐Yes	☐No	☐Unknown	Partially removed scab	☐Yes	☐No	☐Unknown

Pain at any lesion site: ☐YES ☐NO If yes, pain score (0–10: 0 is no pain; 10 is worst imaginable pain: [___] [___]

1e. SIGNS AND SYMPTOMS ON ADMISSION

Sore throat	☐Yes	☐No	☐Unknown	Chest pain	☐Yes	☐No	☐Unknown
Muscle aches (myalgia)	☐Yes	☐No	☐Unknown	Joint pain (arthralgia)	☐Yes	☐No	☐Unknown
Headache	☐Yes	☐No	☐Unknown	Fatigue/malaise	☐Yes	☐No	☐Unknown
Visual symptoms/Keratitis	☐Yes	☐No	☐Unknown	Psychological disturbance	☐Yes	☐No	☐Unknown
Vomiting/nausea	☐Yes	☐No	☐Unknown	Diarrhoea	☐Yes	☐No	☐Unknown
Genital ulcers	☐Yes	☐No	☐Unknown	Dizziness	☐Yes	☐No	☐Unknown
Anal ulcers	☐Yes	☐No	☐ Unknown	Decreased urine output	☐Yes	☐No	☐Unknown

Lymphadenopathy
If yes,

Axillary	☐Yes, painful	☐Yes, not painful	☐NO
Cervical	☐Yes, painful	☐Yes, not painful	☐NO
Inguinal	☐Yes, painful	☐Yes, not painful	☐NO
Other	☐Yes, painful	☐Yes, not painful	☐NO

Specify: _____

MODULE 2. Follow up during hospital stay or on follow-up visits – daily or as frequent as possible

Date of follow up [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

LESION ASSESSMENT (daily):

Have any new lesions appeared in the last 24 hours? ☐YES ☐NO

Number of lesions on the entire body that are NOT resolved (resolved = scabbed and desquamated):

☐0 ☐1–5 ☐6–25 ☐26–100 ☐>100

Number of lesions on the right leg (to the hip crease, including front and back of foot and leg): [__][__][__][__]

Number of lesions on the right arm (including hand and shoulder): [__][__][__][__]

Number of lesions on the left leg (to the hip crease, including front and back of foot and leg): [__][__][__][__]

Number of lesions on the left arm (including hand and shoulder): [__][__][__][__]

Number of lesions on the genitals (from hip crease to hip crease): [__][__][__][__]

Does the patient have active lesions in the following areas:

Face	☐Yes ☐No ☐Unknown	Palms of hands	☐Yes ☐No ☐Unknown
Nose	☐Yes ☐No ☐Unknown	Arms	☐Yes ☐No ☐Unknown
Mouth	☐Yes ☐No ☐Unknown	Forearms	☐Yes ☐No ☐Unknown
Chest	☐Yes ☐No ☐Unknown	Thighs	☐Yes ☐No ☐Unknown
Abdomen	☐Yes ☐No ☐Unknown	Legs	☐Yes ☐No ☐Unknown
Back	☐Yes ☐No ☐Unknown	Soles of feet	☐Yes ☐No ☐Unknown
Perianal	☐Yes ☐No ☐Unknown	Other	☐Yes ☐No ☐Unknown
Genitals	☐Yes ☐No ☐Unknown	Specify where:	_____

Types of lesions on the body:

Early vesicle	☐Yes ☐No ☐Unknown	Ulcerated lesion	☐Yes ☐No ☐Unknown
Small pustule	☐Yes ☐No ☐Unknown	Crusting of a mature lesion	☐Yes ☐No ☐Unknown
Umbilicated pustule	☐Yes ☐No ☐Unknown	Partially removed scab	☐Yes ☐No ☐Unknown

Pain at any lesion site: ☐YES ☐NO
If yes, pain score (0–10: 0 is no pain; 10 is worst imaginable pain: [___] [___]

2a. VITAL SIGNS *(record most abnormal value between 00:00 to 24:00) or any value at visit*

Temperature [_][___].[_]°C **Heart rate** [___][___][_]beats/min **Respiratory rate** [_][___]breaths/min

BP [_] [_] [_](systolic) [___][_][_](diastolic) mmHg **Alert Voice Pain Unresponsive** (circle one)

MODULE 3. Complete at discharge/death/last follow up

3a. DIAGNOSTIC/PATHOGEN TESTING please list all diagnostic tests for pathogens

Date	Specimen type	Test performed	Result
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Lesion/crust swab O Urine O Stool/rectal swab O Blood O Other, specify: ____________	O Monkeypox PCR O Orthopoxvirus PCR O Other____________	O Positive O Negative O Unknown
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Lesion/crust swab O Urine O Stool/rectal swab O Blood O Other, specify: ____________	O Monkeypox PCR O Orthopoxvirus PCR O Other____________	O Positive O Negative O Unknown
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Lesion/crust swab O Urine O Stool/rectal swab O Blood O Other, specify: ____________	O Monkeypox PCR O Orthopoxvirus PCR O Other____________	O Positive O Negative O Unknown
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Lesion/crust swab O Urine O Stool/rectal swab O Blood O Other, specify: ____________	O Other____________	O Positive O Negative O Unknown
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Lesion/crust swab O Urine O Stool/rectal swab O Blood O Other, specify: ____________	O Other____________	O Positive O Negative O Unknown
_D_ _D_ /_M_ _M_ /202 _Y_	O Nasal/NP swab O Throat swab O Combined nasal/NP + throat swab O Sputum O BAL O ETA O Lesion/crust swab O Urine O Stool/rectal swab O Blood O Other, specify: ____________	O Other____________	O Positive O Negative O Unknown

3b. COMPLICATIONS if hospitalized, at any time during hospitalization, did the patient experience:								
Shock	☐Yes	☐No	☐Unknown	Bacteraemia	☐Yes	☐No	☐Unknown
Seizure	☐Yes	☐No	☐Unknown	Bacterial super-infection	☐Yes	☐No	☐Unknown
Meningitis/encephalitis	☐Yes	☐No	☐Unknown	Bleeding	☐Yes	☐No	☐Unknown
Anaemia	☐Yes	☐No	☐Unknown	Abscess	☐Yes	☐No	☐Unknown
Cardiac arrhythmia	☐Yes	☐No	☐Unknown	Myocarditis/pericarditis	☐Yes	☐No	☐Unknown
Cardiac arrest	☐Yes	☐No	☐Unknown	Acute renal injury	☐Yes	☐No	☐Unknown
Pneumonia	☐Yes	☐No	☐Unknown	Pancreatitis	☐Yes	☐No	☐Unknown
Cellulitis	☐Yes	☐No	☐Unknown	Liver dysfunction	☐Yes	☐No	☐Unknown
Acute respiratory distress syndrome (ARDS)	☐Yes	☐No	☐Unknown	Cardiomyopathy	☐Yes	☐No	☐Unknown
Stroke: ischaemic stroke	☐Yes	☐No	☐Unknown	Ocular infection	☐Yes	☐No	☐Unknown
Necrotizing infection	☐Yes	☐No	☐Unknown	Other If yes, specify	☐Yes	☐No	☐Unknown _____

3c. MEDICATION while hospitalized or at discharge, were any of the following administered:

Oral/orogastric fluids? ☐Yes ☐No ☐Unknown **Intravenous fluids?** ☐Yes ☐No ☐Unknown

Experimental orthopox antiviral? ☐Yes ☐No ☐Unknown

If yes: ☐Brincidofovir ☐Cidofovir ☐Tecovirimat

☐Other, specify: _____

If yes: side effect reported? ☐Yes ☐No ☐Unknown

If yes, specify: _____

Antibiotic? ☐Yes ☐No ☐Unknown

If yes, specify : ☐Ceftriaxone ☐Doxycycline ☐Amoxicillin-clavulanate ☐ Other_____

Antifungal agent? ☐Yes ☐No ☐Unknown

Other ☐Yes ☐No ☐Unknown

Other experimental agent? ☐Yes ☐No ☐Unknown

If yes, specify:_____

_____

_____

3d. SUPPORTIVE CARE for those hospitalized, at any time during hospitalization, did the patient receive/undergo:

ICU or high dependency unit admission? ☐Yes ☐No ☐Unknown **If yes,** total duration: _____days
Date of ICU admission [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/A
Date of ICU discharge [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐In ICU at outcome ☐N/A

Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes,** complete all: Total duration:___days
Oxygen flow: ☐1–5 L/min ☐6–10 L/min ☐11–15 L/min ☐ > 15 L/min
Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask

Non-invasive ventilation? (e.g. BiPAP, CPAP) ☐Yes ☐No ☐Unknown **If yes,** total duration:_____days

Invasive ventilation (any)? ☐Yes ☐No ☐Unknown **If yes,** total duration: _____days
Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown **If yes,** total duration: ___days
Inotropes/vasopressors? ☐Yes ☐No ☐Unknown **If yes,** total duration: ___days
Renal replacement therapy (RRT) or dialysis? ☐Yes ☐No ☐Unknown

3e. OUTCOME

Outcome: ☐Discharged alive ☐Hospitalized ☐Transfer to other facility ☐Death ☐Palliative discharge ☐Unknown
Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Unknown
If discharged alive, ability to self-care at discharge versus before illness: ☐Same as before illness ☐Worse ☐Better ☐Unknown

Number of lesions on the entire body that are NOT resolved (resolved = scabbed and desquamated):
☐0 ☐1–5 ☐6–25 ☐26–100 ☐>100

Residual symptoms _____

3f. CLINICAL INCLUSION CRITERIA

Suspected	☐Yes	☐No
Probable	☐Yes	☐No
Confirmed	☐Yes	☐No

** See definitions here:*
Surveillance, case investigation and contact tracing for Monkeypox: Interim guidance (who.int)