



ชื่อ นามสกุล ผู้ป่วย

ชื่อสถานพยาบาล

Global Clinical Data Platform MONKEYPOX CASE REPORT FORM (CRF) MODULE 5.1

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 \leq 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 <u>mpox registration form</u>, 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 <u>monkeypox clinicaldataplatform@who.int</u> for any further information.



MODULE 5. Pregnancy module

To be completed for women who are either:

- currently pregnant, or .
- recently pregnant (within 21 days of pregnancy outcome). .

At the end of pregnancy, please complete Module 5.2 (regardless of discharge from monkeypox care).

Complete within 24 hours from baseline visit at hospital or outpatient service.

5a. PREGNANCY STATUS	AT BASE	LINE VIS	T		
Pregnant not in labour					
Pregnant in labour					
Postpartum	□Yes If yes, how many days? [days]			□No	
Breastfeeding	□Yes		□No		
Post-abortion/miscarriage					
Number of fetuses	□1 □	2 🗆 3	□Other [number]	□Unknown	
Was this an IVF pregnancy?	? □Yes	□No	□Unknown		
		_			

5b. ABORTION OR MISCARRIAGE (prior to admission)

Date of induced abortion or spontaneous abortion/missed abortion/miscarriage

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

Were symptoms of monkeypox present at the time? UYes No □Unknown

5c. OBSTETRIC HISTORY

Number of previous pregnancies beyond 22 weeks' gestation [number] Number of previous vaginal deliveries [number] Number of previous caesarean deliveries [number]					
Please indicate if any apply to previous	s deliveries:				
Preterm birth (< 37 weeks 'gestation)	□Yes □No □Unknown				
Congenital anomaly	□Yes □No □Unknown				
Stillborn	□Yes □No □Unknown				
Neonatal death (≤ 7 days)	□Yes If yes, how many days? [_Day _] □No □Unknown				
Weight	□< 2500 g □ > 4500 g				

5d. ALCOHOL, DRUGS – RISK FACTORS DURING THIS PREGNANCY				
Alcohol consumption	□Yes If yes, number of alcohol units weekly			
□No □Unknown				
Illicit/recreational drug use	□Yes If yes, number of times in a week			
	□No □Unknown			
Smoking use	□Yes If yes, number of cigarettes a day			

MPX case report form (CRF): module 5, 27 March 2023

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			Module 5 – page
THIS PREGN		orior to onset o	f current illness episode)
□Yes	□No	□Unknown	If yes, specify generic name:
□Yes	□No	□Unknown	If yes, specify generic name:
□Yes	□No	□Unknown	If yes, specify generic name:
□Yes	□No	□Unknown	If yes, specify number of doses
□Yes	□No	□Unknown	If yes, specify generic name:
	□Yes □Yes □Yes □Yes	□Yes □No □Yes □No □Yes □No □Yes □No □Yes □No	□Yes □No □Unknown □Yes □No □Unknown □Yes □No □Unknown

5f. FETAL HEART RATE – if applicable (first available data at presentation/admission)					
Fetal heart rate (FHR)	[][][] beats/min				
	ATERNAL OUTCOME AT DISC ge or at recovery from monkeypo				
Pregnancy outcome	 Pregnancy ongoing Live birth Spontaneous abortion^a Induced abortion^a Macerated stillbirth^a Fresh stillbirt ^a Post-abortion/postpartum on admission^a ^a Date of pregnancy outcome [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] 				
Complications during the	Gestational diabetes	□Yes	□No	□Unknown	
course of pregnancy	Gestational hypertension	□Yes	□No	□Unknown	
	Anaemia (Hb < 11 g/dL)	□Yes	□No	□Unknown	
	Obstetric infections	□Yes	□No	□Unknown	
	Intrauterine growth restriction	□Yes	□No	□Unknown	
	Bleeding	□Yes	□No	□Unknown	
	Pre-eclampsia	□Yes	□No	□Unknown	
	Eclampsia	□Yes	□No	□Unknown	
	Other (specify)				
Maternal death	□Yes □No				
In the event of maternal death and the patient is participating in WHO emergency use protocol for tecovirimat for monkeypox under MEURI framework please also complete Module 4.	If yes, what was the underlying cause of death? Abortive outcome Hypertensive disorders in pregnancy, childbirth and the puerperium Obstetric haemorrhage Pregnancy-related infection Unanticipated complications of management (e.g. anaesthesia-related complications) Indirect maternal death Obstetric death of unspecified cause Deaths from a coincidental cause (e.g. motor vehicle accident) Other obstetric complication not included in above causes				

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