Dr Janet Diaz
Lead, Clinical Management and Operations Unit
Health Emergencies Programme, WHO
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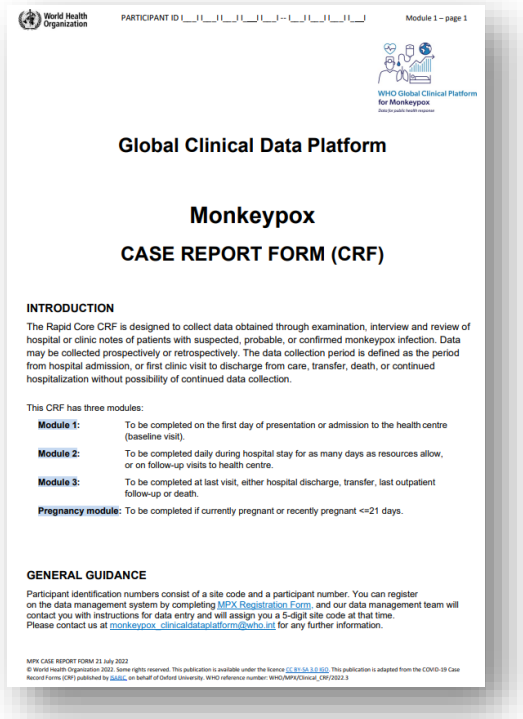
WHO Global Clinical Platform for Monkeypox

Data for public health response

World Health Organization

HEALTH EMERGENCIES programme

Clinical data platform for monkeypox


World Health Organization PARTICIPANT ID Module 1 – page 1

WHO Global Clinical Platform for Monkeypox
Data for public health response

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 (baseline visit).

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, transfer, last outpatient follow-up or death.

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 completing MPX Registration Form, 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 further information.

MPX CASE REPORT FORM 21 July 2022

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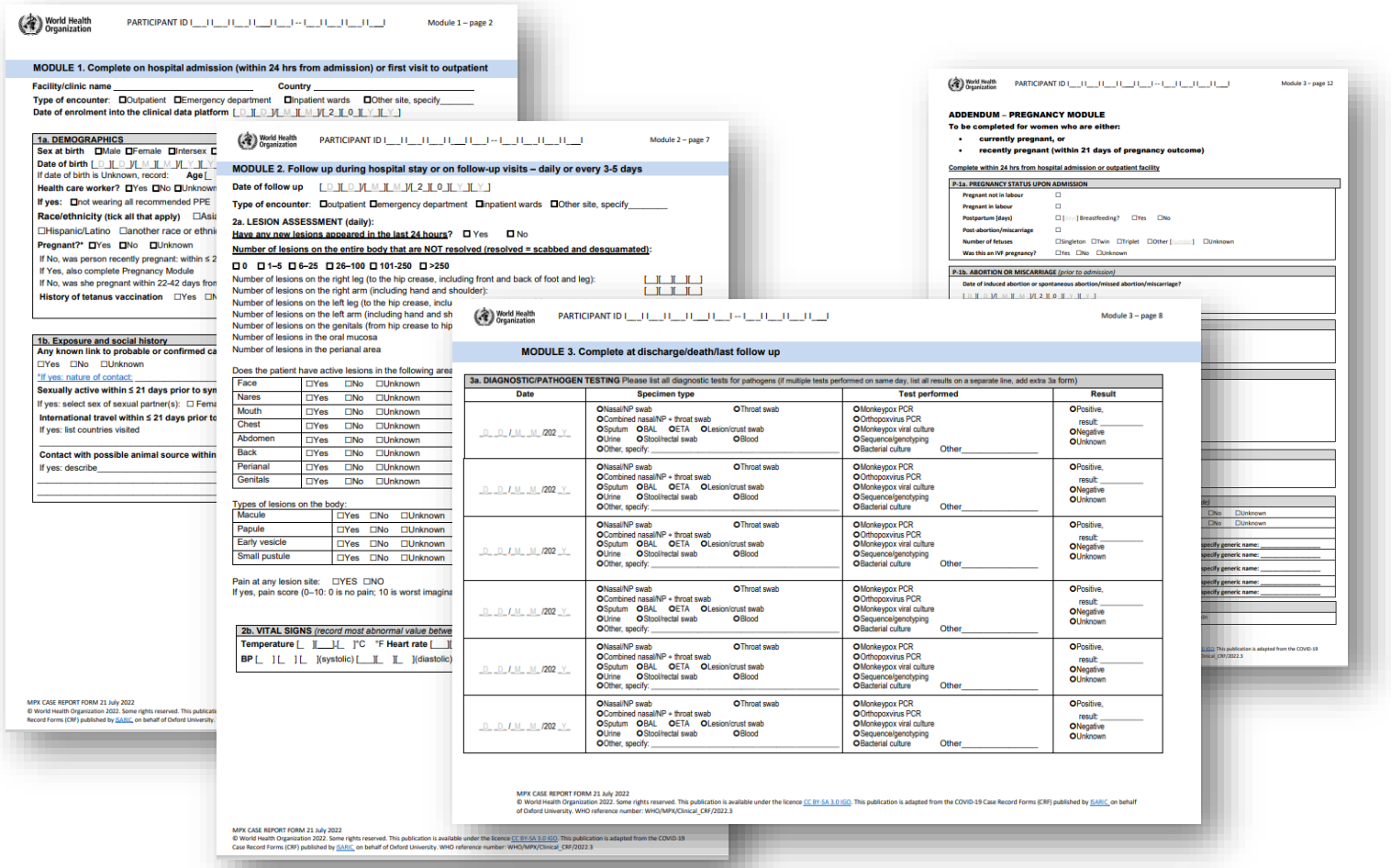
The objectives of the Platform are to:

- Describe the clinical characteristics of monkeypox;
- Assess the variations in clinical characteristics of monkeypox;
- Identify the association of clinical characteristics of monkeypox with outcomes; and if available with vaccination and treatments
- Describe the temporal trends in clinical characteristics of monkeypox.

WHO invites Member States, health facilities and other entities to participate in the global effort to collect anonymized clinical data relating to suspected or confirmed cases of monkeypox and contribute data to the **WHO Global Clinical Platform.**

WHO has developed a clinical characterization case report forms (CRF) to standardize data collection of clinical features of monkeypox among outpatient and hospitalized cases.

CRF for monkeypox: harmonized data collection



3 Modules:

Module 1:
Baseline Visit
Module 2:
Follow up visits, inpatient days
Module 3:
Endpoints
(recovery, discharge, transfer death)

Additional Module:
Pregnancy module

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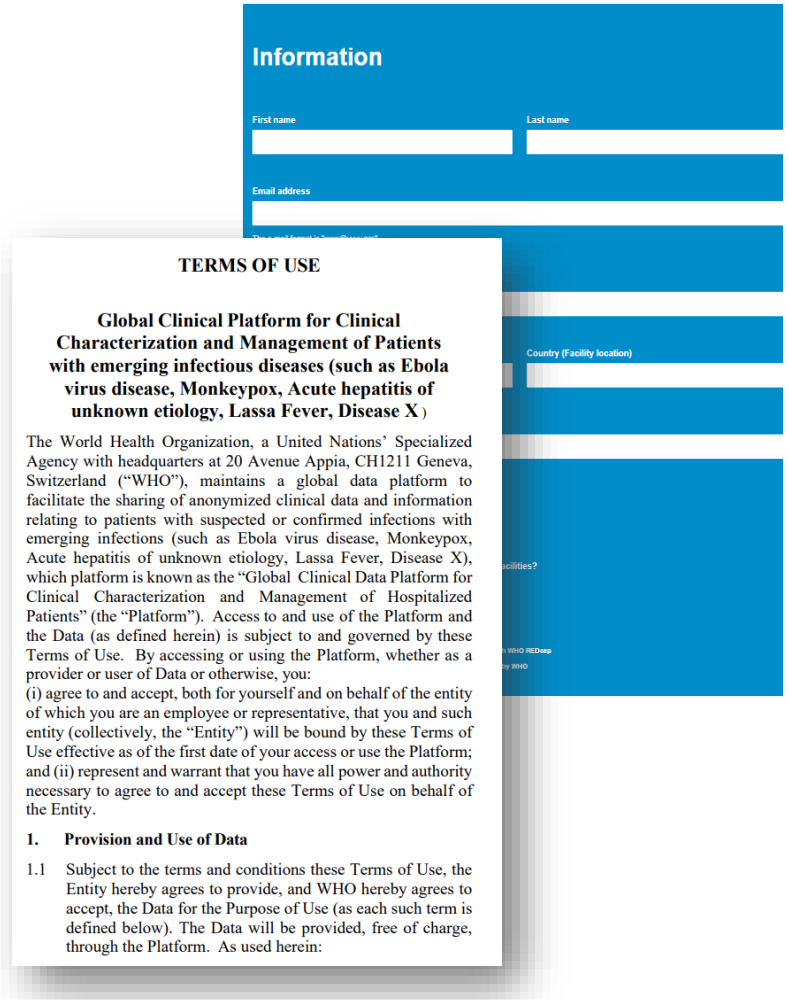
Options to contribute clinical anonymized data:

- Directly into the electronic WHO Platform
- Sharing established databases
- From printed paper CRFs, with data entered in the WHO Platform thereafter.

Steps to contribute to the platform:

- Create your profile by registering.
- Review the **terms of use**.
- After a few days, you will receive an email with the login credentials to access the WHO Platform, or, if you are sharing an established database, additional instructions to contribute data.

For any additional questions, please contact: monkeypox_clinicaldataplatform@who.int



Collecting vaccination data

World Health Organization

PARTICIPANT ID I___I I___I I___I I___I I___I -- I___I I___I I___I I___I I___I

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1h. History of smallpox or monkeypox vaccination

History of smallpox vaccination before 1980? ☐Yes ☐No ☐Unknown

Source of information: ☐Documented evidence (vaccine card/vaccine passport/facility-based record/other)

☐Visible scar ☐Recall

History of smallpox or monkeypox vaccination in past year ☐Yes ☐No ☐Unknown

If yes, number of doses received: ☐1 ☐ 2 ☐3 ☐Unknown

Source of information: ☐Documented evidence (vaccine card/vaccine passport/facility-based record/other) ☐Recall

Dose 1, Date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]specify ☐Jynneos ☐IMVANEX ☐ Imvamune

☐ ACAM2000 ☐APSV: Aventis Pasteur smallpox vaccine ☐LC16m8 ☐other _____

Dose 2, Date [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]specify ☐Jynneos ☐IMVANEX ☐ Imvamune

☐ ACAM2000 ☐APSV: Aventis Pasteur smallpox vaccine ☐LC16m8 ☐other _____

Dose 3, Date [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]specify ☐Jynneos ☐IMVANEX ☐ Imvamune

☐ ACAM2000 ☐APSV: Aventis Pasteur smallpox vaccine ☐LC16m8 ☐other _____

Collecting lesion and symptom description

1e. Rash evaluation (baseline visit)

Number of lesions on the entire body that are NOT resolved (resolved = scabbed and desquamated and fresh layer of skin has formed underneath):

☐0 ☐ 1–5 ☐ 6–25 ☐ 26–100 ☐ 101-250 ☐ > 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): [__][__][__][__]
Number of lesions in the oral mucosa [__][__][__][__]
Number of lesions in the perianal area [__][__][__][__]

Does the patient have active lesions in the following areas:

Face	☐Yes	☐No	☐Unknown	Palms of hands	☐Yes	☐No	☐Unknown
Nares	☐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: [___] [___]

1f. SIGNS AND SYMPTOMS (first encounter)

Sore throat	☐Yes	☐No	☐Unknown	Proctitis	☐Yes	☐No	☐Unknown
Muscle aches (myalgia)	☐Yes	☐No	☐Unknown	Pain with swallowing	☐Yes	☐No	☐Unknown
Headache	☐Yes	☐No	☐Unknown	Difficulty swallowing	☐Yes	☐No	☐Unknown
Ocular symptoms (pain, redness, visual loss)	☐Yes	☐No	☐Unknown	Pain with urination	☐Yes	☐No	☐Unknown
Fatigue/malaise	☐Yes	☐No	☐Unknown	Urethritis	☐Yes	☐No	☐Unknown
Oral Pain	☐Yes	☐No	☐Unknown	Chest pain	☐Yes	☐No	☐Unknown
Nausea	☐Yes	☐No	☐Unknown	Decreased urine output	☐Yes	☐No	☐Unknown
Vomiting	☐Yes	☐No	☐Unknown	Dizziness	☐Yes	☐No	☐Unknown
Diarrhoea	☐Yes	☐No	☐Unknown	Joint pain (arthralgia)	☐Yes	☐No	☐Unknown
Rectal pain	☐Yes	☐No	☐Unknown	Psychologic disturbance	☐Yes	☐No	☐Unknown

Lymphadenopathy: ☐Yes ☐No ☐Unknown
If yes,
Axillary ☐Present ☐Present and tender
Cervical ☐Present ☐Present and tender
Inguinal ☐Present ☐Present and tender
Other ☐Present ☐Present and tender
Specify other: _____

Collecting therapeutic data

World Health Organization

PARTICIPANT ID |___|___|___|___|___|___|___| -- |___|___|___|___|___|

3d. MEDICATIONS at any time, were any of the following administered:

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

Experimental orthopox antiviral? ☐Yes ☐No ☐Unknown

☐**Tecovirimat:** First date given: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Dose: _____ Frequency: _____ Route:_____ Duration: _____ in days _____

☐**Brincidofovir:** First date given: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Dose: _____ Frequency: _____ Route: _____ Duration: _____ in days _____

☐**Cidofovir:** First date given: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Dose: _____ Frequency: _____Route: _____ Duration: _____ in days _____

Other experimental agent: First date given: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Dose: _____ Frequency: _____Route: _____ Duration: _____ in days _____

If yes, specify: _____

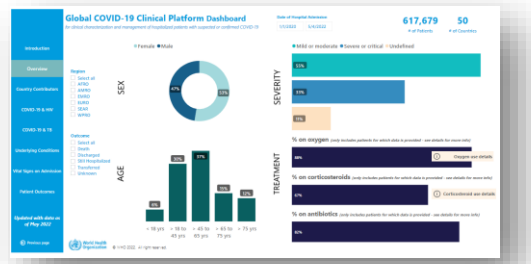
Global Participation

As learnt from COVID-19 **Global data sharing** affords the international medical community an opportunity to garner clinical data from all over the world for global, regional and country reports.

Provides real time descriptive dashboard on clinical characterization at global and regional level.

Provides regular analysis on associations with outcomes, including vaccination and use of treatments.

Informs clinical management guidelines in real time



The WHO Global Clinical Platform for monkeypox

Contacts:
monkeypox_clinicaldataplatform@who.int
diazj@who.int
cramond@who.int
thwins@who.int

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