COHORT EVENTS MONITORING (CEM) STUDY FOR THE ASSESSMENT OF SAFETY PROFILE OF MVA-BN (JYNNEOS) VACCINE IN ADULT PERSONNEL AND STAFF IN THE PALM-007 STUDY IN DEMOCRATIC REPUBLIC OF THE CONGO

Protocol v2.0, 07Oct2023

NCT05734508

COHORT EVENTS MONITORING (CEM) STUDY FOR THE ASSESSMENT OF SAFETY PROFILE OF MVA-BN (JYNNEOS) VACCINE IN ADULT PERSONNEL AND STAFF IN THE PALM-007 STUDY IN DEMOCRATIC REPUBLIC OF THE CONGO

Abbreviated title:	CEM-JYNNEOS
Full Title:	Cohort events monitoring (CEM) study for the assessment of safety profile of MVA-BN (Jynneos) vaccine in adult personnel and staff in the PALM-007 study in Democratic Republic Of The Congo
Protocol number:	PALM 008
Version of protocol:	Version 2.0 dated 07 Oct 2023
Principal Investigator:	Nsengi Ntamabyaliro, MD, MSc PhD
Co-Principal Investigator:	Aline Engo Biongo, MD

Table of contents

List of Tables

1. Background and rationale

Background

Monkeypox is a viral zoonotic infection meaning that it can spread from animals to humans. It can also spread through human-to-human contact. The PALM-007 study will be conducted in the Democratic Republic of the Congo (DRC) to assess the efficacy and safety of tecovirimat, a potential treatment drug for Monkeypox in hospitalized patients. Given their proximity to the patient, PALM-007 personnel and staff associated with the study are at high risk of contracting Monkeypox disease. Therefore, there is a need to protect them by vaccination as recommended by the World Health Organization (WHO). (1)

The MVA-BN vaccine, which can be given subcutaneously (2), has been approved by regulatory authorities in the USA (JYNNEOS)(3) and Europe (Imvanex)(4) for prevention of Monkeypox infection..

The Ministry of Health, having given temporary authorization for the use of this vaccine, believes it is important to monitor vaccinated individuals and thus determine the safety profile of this vaccine in the Congolese adult population. This vaccination will therefore be accompanied by a safety follow-up of all participants.

Potential benefits

Data available to date suggest that MVA-BN vaccine is highly effective in the prevention of Monkeypox and has been approved by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA).

A study on macaques has shown that 2 doses of MVA-BN induce 100% protection against a lethal challenge of aerosolized Monkeypox virus(5). A separate study in cynomolgus macaques demonstrated no significant difference between levels of neutralizing antibodies in animals vaccinated with ACAM2000 (a second-generation smallpox vaccine) and those vaccinated with 2 doses of MVA-BM(6). Preclinical studies and Phase I/II clinical trials of MVA-BN have suggested that 2 doses of vaccine are immunogenic generating antibody levels considered protective against smallpox and, by extrapolation, against monkeypox as well.(7)

In the DRC, the MVA-BN vaccine has received temporary authorization for use. Therefore, PALM-007 staff may benefit from participation in this study, in the form of protection against Monkeypox infection.

Possible risks

Like any active product, the MVA-BN vaccine can cause side effects. Data from several clinical trials show that MVA-BN has a favorable adverse effect profile. There are, however, some common mild adverse events (AEs), such as local site reactions and flu-like symptoms. Other local side effects may include erythema, pain, edema, pruritus, hyperpigmentation and induration. Other systemic side effects can include fatigue, headache, myalgias, nausea, chills, fever. The frequency of AEs, especially local site reactions, in people who have never been vaccinated against smallpox and vaccinated for the first time (with MVA-BN) does not appear to be significantly higher than the frequency of AEs in those who have previously been vaccinated.

2. Objectives of the study

2.1. General objective

The overall objective of this observational study is to monitor and assess the safety profile of the MVA-BN vaccine among staff and study personnel of the PALM-007 study in DRC.

2.2. Specific objectives

The specific objectives are as follows:

- Estimate the incidence of serious adverse events (SAEs) in all individuals vaccinated with the MVA-BN vaccine
- Estimate the incidence of AEs after each dose of MVA-BN vaccine.

3. Methods

3.1. Study design

This is a study of the safety of the MVA-BN vaccine through a one-arm prospective observational cohort study that will be conducted under the coordination of the National Pharmacovigilance Center of the DRC. After informed consent is obtained, study participants

will receive two doses of vaccine and will be actively followed up to the 28th days after their last dose of MVA-BN vaccine.

3.2. Study population

Participants 18 years and older will be recruited from personnel of the PALM-007 Monkeypox study and staff associated with the study in the DRC. Participation in the study will be voluntary and up to 1000 participants may be enrolled at the PALM-007 study sites or in Kinshasa.

3.2.1. Inclusion criteria

- Provides written informed consent
- 18 years of age or older
- At high risk for Monkeypox infections
- Personnel and staff associated with the PALM 007-Monkeypox study sites in the DRC
- Willingness and ability to communicate AEs to study personnel.

3.2.2. Exclusion criteria

- Allergy to MVA-BN or any of its components
- Pregnant or breastfeeding women
- Fever (axillary temperature ≥37.5°celsius)
- People who have already received the MVA-BN vaccine (in routine vaccination or another study involving this vaccine)
- Participants who, in the judgement of the investigator, will be at significantly increased risk as a result of participation in the study
- Individuals with any condition or circumstance that would render them unable to comply with study procedures (e.g., not reachable by phone)

3.4 Withdrawal from the study

Participants will have the right to withdraw from the study for any reason at any time. This will not affect their staff position on the PALM-007 study. People who have had a serious allergic reaction to the first dose of MVA-BN will not receive a second study dose but will be followed t as described in section 4.2. If participants had a previous serious allergic reaction to any of the components of MVA-BN prior to joining this study, they may be at increased risk of serious allergic reactions. Therefore, these participants will be excluded from the study.

If a participant develops monkeypox infection, he/she will be withdrawn from the study and will receive the best treatment available for this disease. If this occurs between the first and second dose of vaccine, the participant will not receive the second dose.

If a participant decides to withdraw from the study, no further data will be collected about him/her. However, data collected up to the time of withdrawal will be used in analyses.

3.5 Pregnant and breastfeeding women

Available data on the risk of MVA-BN (JYNNEOS) vaccine on embryo-fetal and postnatal development is insufficient; therefore, pregnant and breastfeeding women will be excluded from the study. A pregnancy test will be performed at screening and on Day 28 for all women of childbearing potential. If a woman becomes pregnant following receipt of the vaccine, her pregnancy will be monitored. She will be followed up for the full duration of the pregnancy. She will follow antenatal visits in the health facilities and the schedule recommended by the national policy. She will be requested to communicate to the study staff all AEs for assessment and reporting purposes. The outcome and the pregnancy will be assessed: the newborn will be examined, and all malformation/birth defect reported as serious adverse event.

3.3. Study sites

The study will be conducted at all sites of the PALM-007 study and in Kinshasa, at the National Institute of Biomedical Research (INRB). Participation in the study will be offered to the personnel and staff of the DRC PALM-007 study.

4. Study flow

4.1. Screening and enrollment of participants

All personnel and staff of the PALM-007 study will be offered the opportunity to participate in the study by reviewing and signing the informed consent. After signing informed consent, participants will be examined. The following parameters will be assessed:

- Anthropometric measurements (weight, height)
- Vital signs: temperature (axillary), blood pressure, heart rate and respiratory rate
- Medical history, including history of orthopox virus disease, vaccination, current co-morbidities and medication(s)
- Physical examination

- Pregnancy test will be done for all women of childbearing potential.

If a participant has met all eligibility criteria, they will be enrolled and will receive the vaccine as specified below. Participants who are excluded because of fever can be rescreened and included after resolution of the fever and its cause.

Enrolled participants will receive the MVA-BN vaccine by subcutaneous injection of 0.5 mL in the shoulder (left or right). Care must be taken to hold the skin well between 3 fingers and insert the needle at an angle of approximately 45°.

The first dose will be administered at the time of enrollment and the second dose 28 days later.

After each vaccination the participant will remain under observation for 30 minutes. All AEs occurring during this period of observation, will be recorded, and reported to the National Center for Pharmacovigilance and to the ethics committee according to Congolese regulations.

4.2. Follow-up of participants

Participants will be followed until 28 days after the second dose of vaccine. Follow-up visit will be done either in person at INRB (in Kinshasa) and at the Monkeypox treatment centers in the PALM-007 study or by phone calls on Day 3, Day 14, and Day 28 post each vaccination. Study participants will be provided with contact information of vaccine research staff and have the right to contact the research team either directly or by phone if they have any questions about post-vaccination reactions they may be experiencing or if they are concerned. There is a window of +/- one day for each visit except the day of the second dose which can be done on day 28 after the first dose with a window of +7 days. This second dose must not be given before day 28. During each visit, participants will be asked to report to the research team AEs via open-ended questions. All SAEs will be followed-up. SAEs that have not resolved by the end of the per-protocol follow-up period for the subject (Day 28 after second dose) are to be followed until final outcome is known (to the degree permitted by the IRB-approved informed consent form). If it is not possible to obtain a final outcome for an SAE (e.g., the participant is lost to follow-up), the last known status and the reason a final outcome could not be obtained will be recorded by the investigator on an SAE report update and the CRF.

On the day of administration of the second dose of vaccine, vital signs, and physical examination will be done to all participants and a pregnancy test will be done on all women

of childbearing potential prior to vaccine administration. If the pregnancy test is positive, the second dose will not be given, and the participant will be followed up as described in section 3.5. Participants will be instructed to report any AEs that are experienced outside of the protocol defined follow up days. The reporting form of the national pharmacovigilance system of the DRC will be used for reporting. The research team will complete the notification form which will be sent to the National Pharmacovigilance Center (CNPV) by e-mail (scanned copies).

4.3. Safety assessment

4.3.1. Definitions

Adverse event

An AE is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the research.

Adverse drug reaction

All noxious and unintended responses to a medicinal product. The phrase "responses to a "medicinal products" means that a causal relationship between the medicinal product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

Unexpected adverse event

Unexpected adverse event is an event whose nature, severity or outcome is not consistent with the applicable product information (investigator's brochure or package insert)

Serious adverse event

A serious adverse event is any untoward medical occurrence that:

- results in death,
- is life-threatening (places the subject at immediate risk of death from the event as it occurred),
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity,
- is a congenital anomaly/birth defect or,

- is a medically important event.

  NOTE: Medical and scientific judgment should be exercised. Events that significantly jeopardize the subject and/or require intervention to prevent one of the SAE outcomes listed above are generally considered medically important and are thus SAEs.

4.3.2. Severity Grading

The severity of each AE will be graded according to the "Common Terminology Criteria for Adverse Events (CTCAE)" (v 5.0) which can be found at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf

Events that are NOT gradable using the above specified table will be graded as follows:

- Mild = grade 1
- Moderate = grade 2
- Severe = grade 3
- Potentially life threatening = grade 4
- Death = grade 5

This grading will be recorded in the study participant file and the reporting form.

4.3.3. Recording and reporting adverse events

All AEs will be recorded in the participant's file and reported according to Congolese regulations. Serious and unexpected AEs which are fatal or are life threatening, must be reported as per the guidelines on Pharmacovigilance in DRC, i.e., as soon as the reporter (member of the research team) becomes aware of them but no later than 7 calendar days. Update notes may be provided within an additional period not exceeding 15 calendar days. The count of days begins when a reporter becomes aware of the adverse event and the minimum notification conditions are met. All other serious and unexpected AEs must be reported immediately, but within a period not exceeding 15 calendar days. All SAEs will be reported to the Ethics Committee, the national PV Centre and to the manufacturer. The study PI will be responsible for reporting all SAEs. The National PV Centre will send monthly reports to the regulatory authority of DRC, the ACOREP (Autorité Congolaise de Réglementation Pharmaceutique).

Non-serious AEs will be reported as line listing to the national PV center and include in the report to ACOREP.

5. Investigational product (IP) description

The MVA-BN vaccine will be supplied by Bavarian Nordic. It is indicated for the prevention of smallpox and Monkeypox disease. It is a live vaccine produced from the Modified Vaccinia Ankara-Bavarian Nordic strain (MVA-BN), an attenuated and non-replicating orthopox virus. MVA-BN is cultured in primary cells of chicken embryo fibroblasts, (CEF) suspended in a serum-free medium containing no material of direct animal origin, harvested from the CEF cells, purified and concentrated by multiple steps of Tangential Flow Filtration (TFF), including benzonase digestion. Each 0.5 mL dose is formulated to contain 0.5 x 10^8 to 3.95 x 10^8 infectious units of live MVA-BN virus in 10 mM Tris (tromethamine), 140 mM sodium chloride pH 7.7. Each 0.5 mL dose may contain residual amounts of host cell DNA (≤ 20 mcg), protein (≤ 500 mcg), benzonase (≤ 0.0025 mcg), gentamicin (≤ 0.163 mcg) and ciprofloxacin (≤ 0.005 mcg). MVA-BN is a sterile vaccine formulated without preservatives. The bottle caps are not made with natural rubber latex. This vaccine is stored at temperatures between -25°C and -15°C (-13°F and +5°F). The vaccine should be thawed and brought to room temperature before administration. When thawed, MVA-BN is a light yellow to pale white milky suspension. Once thawed, it can be stored at +2°C to +8°C (+36°F to +46°F) for 12 hours. It should not be re-frozen.
For administration, the bottle should be gently shaken before use for at least 30 seconds.

IP accountability

The Study Pharmacist will be responsible for maintaining adequate documentation of vaccine accountability, including receipt of product, temperature monitoring, transport to sites and administration records. The documentation will link the participant's identification number to the lot number of the vaccine administered to them.

6. Ethical consideration

The protocol, the informed consent form, and any document containing information to be provided to participants will be submitted for approval to the Ethics Committee of the School of Public Health of the University of Kinshasa. After approval by the Ethics Committee, the approval of the ACOREP will be required before the start of the study.

The study will be conducted according to the Declaration of Helsinki in its most recent version, Good Clinical Practice, the regulations in force in the DRC, as well as the American regulations governing the protection of human subjects such as 21 CFR 50 and the United States Office for Human Research Protections (OHRP) Informed Consent of Participants.

Informed Consent Process

Consent Procedures and Documentation

All participants will be required to sign or fingerprint the approved informed consent form prior to any study-related procedures.

Informed consent is a process where information is presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is an ongoing conversation between the human research participant and the researchers which begins before consent is given and continues until the end of the participant's involvement in the research. Discussions about the research will provide essential information about the study and include purpose, duration, experimental procedures, alternatives, risks, and benefits. Coercion and undue influence will be minimized by informing participants that their decision to join the study will not affect their position in the PALM 007 study. Participants will be given as much time as they need to read the consent form and ask questions of the investigators. Participants will also be given time to discuss their participation with family members, friends, and other healthcare providers.

Informed consent will be obtained in person by a study team member authorized to obtain consent. The privacy of the participant will be maintained. The consenting investigator and participant will be located in a private area (e.g., clinic consult room). Participants will sign the informed consent document prior to any procedures being done specifically for the study.

A copy of the informed consent document will be given to the participants for their records. The consenting investigator will document the signing of the consent form in the participant's study record. The investigator will confirm that written legally effective consent has been obtained prior to initiating any study interventions.

The rights and welfare of the participants will be protected by emphasizing to them that participation in this study is voluntary and participants may withdraw consent at any time throughout the course of the trial. If participants are not interested in participating or decide to withdraw from the study, their current position will not be affected.

7. Data Management and Monitoring

Data Management Responsibilities

The site investigator is responsible for assuring that the data collected is complete, accurate, and recorded in a timely manner. Source documentation (the point of initial recording of information) should support the data transferred to the electronic data system and, when possible, should be signed and dated by the person recording and/or reviewing the data. All data should be reviewed by the Investigator and co-signed as required.

Data Capture Methods

Study data collected from the participant at study sites will be recorded as paper or CRFs with subsequent transmission to the Data Coordinating Center. Data Coordinating Center personnel shall enter data into an electronic database. Corrections to electronic data systems will be tracked electronically (password protected and through an audit trail) with time, date, individual making the correction, and what was changed.

Source Documents and Access to Source Data/Documents

Source documents include all recordings of observations or notations of clinical activities, and all reports and records necessary for the evaluation and reconstruction of the clinical trial. Source documents may include, but are not limited to, the subject's medical records, subject's diaries, progress notes, pharmacy records, and any other similar reports or records of procedures performed during the subject's participation in the study. Case report forms for this study will also be considered the source documents.

Record Retention

The protocol team is responsible for retaining all essential documents listed in the ICH Good Clinical Practice Guideline. All essential documentation for all study participants is to be maintained by the investigators in a secure storage facility for a minimum of 3 years per NIAID policies or per in-country local or federal regulatory requirements (whichever is longer). These records are also to be maintained in compliance with IRB/EC and local medical records retention requirements, whichever is longest. All stored records are to be kept confidential to the extent required by applicable laws in the jurisdiction in which they are stored.

Site Monitoring Plan

As per ICH-GCP 5.18, clinical protocols are required to be adequately monitored by the study sponsor. This study monitoring will be conducted according to the "NIAID Intramural Clinical Monitoring Guidelines." If feasible, monitors under contract to the NIAID/Office of Clinical Research

Policy and Regulatory Operations (OCRPRO) or their designee may visit the clinical research site to monitor aspects of the study in accordance with the appropriate regulations and the approved protocol. The objectives of a monitoring visit would be: 1) to verify the existence of signed informed consent documents and documentation of the Informed Consent Form process for each monitored participant; 2) to verify the prompt and accurate recording of all monitored data points, and prompt reporting of all SAEs; 3) to compare data abstracts with individual participants' records and source documents (participants' charts, medical progress notes, test results and any other relevant original participant information); and 4) to help ensure investigators are in compliance with the protocol. The monitors also may inspect the clinical site regulatory files to ensure that regulatory requirements (Office for Human Research Protections [OHRP]) and applicable guidelines (ICH-GCP) are being followed. During the monitoring visits, the investigator (and/or designee) and other study personnel should be available to discuss the study progress and monitoring visit.

Confidentiality and Privacy:

All records will be kept confidential to the extent provided by local laws in the jurisdictions in which the study is conducted. Study monitors and other authorized individuals may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records. Records will be kept locked, and data will be coded. Any personally identifiable information maintained for this study will be kept on restricted-access computers and networks. Personally identifiable information will only be shared with individuals authorized to receive it under this protocol. Individuals not authorized to receive personally identifiable information will be provided with coded information only, as needed. Clinical information will not be released without written permission of the participant, except as necessary for monitoring by the IRB/EC, NIAID, local regulatory agencies, the pharmaceutical supporter, or other authorized individuals.

The confidentiality of all participants will be protected in accordance with Good Clinical Practice.

Compensation

Participants will be vaccinated at the workplace; no compensation will be provided. However, if there is a need for an unscheduled visit, compensation of $5 US will be provided for transportation. During follow-up of pregnancies, and if necessary, the site may assist the pregnant women in the fees related to antenatal consultation and ultrasounds. A maximum of $5 may be given to the participant for each prenatal consultation and a maximum of $10 for each ultrasound.

8. Statistical Considerations

The study will vaccinate 1000 participants to estimate the following:

1) The frequency and severity of solicited SAEs up to 14 days after each dose of the vaccination.
2) The frequency and severity of AEs from the first vaccine dose to 28 days after the second vaccine dose.

Statistical analysis

The proportion of SAEs will be estimated along with 95% confidence intervals using the Clopper-Pearson method at:

- 14 days after the first vaccine administration, and
- 28 days after the vaccine boost.

The proportion of AEs will be estimated along with 95% confidence intervals using the Clopper-Pearson method at:

- 14 days after the first vaccine administration, and
- 28 days after the vaccine boost.

The severity of events will be tabulated and analyzed for reporting.

Sample size justification

The sample size was determined according to the expected number of staff to be vaccinated, in addition to ensuring adequate precision of 95% confidence intervals of the estimates of the frequency of SAEs and AEs. With 1000 participants, the expected halfwidth of the confidence interval will not be greater than 0.05.

9. Schedule of activities

Table 9.1 Schedule of Activities

Evaluation/Procedure	Screen	Follow-up						
Visit	**1**	**2**	**3**	**4**	**4.1**	**5**	**6**	**7**
Day	**0**	**3±1[b]**	**14±1[b]**	**28±1[b]**	**28+7**	**3±1[c]**	**14±1[c]**	**28±1[c]**
Informed consent	X							
Eligibility (inclusion/exclusion) assessment	X							
Demographics	X							
Medical history	X							
Medication review	X	X	X	X	X	X	X	X
Weight and Height	X							
Pregnancy test (serum or urine)*	X				X			
Vital Signs	X				X			
Physical examination	X				X			
Vaccination	X				X			
Assessment of AEs/SAEs	X	X	X	X	X	X	X	X

[b] Days after First dose of vaccine.

[c] Days after second dose of vaccine

* Pregnancy test for women of childbearing potential

10. Abbreviations

ACOREP	Autorité Congolaise de Réglementation harmaceutique
DNA	DesoxyriboNucleic Acid
CEF	Chicken Embryo Fibroblasts
EC	Ethics Committee
CEM	Cohort Event Monitoring
CNPV	Centre National de Pharmacovigilance
CRF	Case report Form
CTCAE	Common Terminology Criteria for Adverse Events
AE	Adverse Event
SAE	Serious Adverse Event
EMA	European Medicines Agency
ESP	Ecole de Santé Publique
FDA	Food and Drug Administration
GCP	Good Clinical Practices
ICH	International consil on harmonization
INRB	Institut National de Recherche Biomédicale
IRB	Institutional review board
MVA-BN	Modified Vaccinia Ankara-Bavarian Nordic
NIAID	National Institute of Allergy and Infectious Diseases
OCPRO	Office of Clinical Research Policy and Regulatory Operations
OHRP	Office for Human Research Protections
WHO	World health Organization
PALM	Pamoja Tulinde Maisha
IP	Investigational Product
PV	Pharmacovigilance
DRC	Democratic Republic of the Congo
TFF	Tangential Flow Filtration

11. References

1. WHO Smallpox Eradication programme. Vaccines and immunization for monkeypox. 2022. p. 1–28.

2. U.S. Food and Drug Administration. Package Insert JYNNEOS [Internet]. 2022 [cited 2022 Oct 6]. p. 1–11. Available from: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.fda.gov/media/131078/download

3. BAVARIAN NORDIC ANNOUNCES U.S. FDA APPROVAL OF JYNNEOS™ (SMALLPOX AND MONKEYPOX VACCINE, LIVE, NON-REPLICATING) FOR PREVENTION OF SMALLPOX AND MONKEYPOX DISEASE IN ADULTS [Internet]. 2019 [cited 2022 Sep 24]. Available from: https://www.drugs.com/newdrugs/fda-approves-jynneos-smallpox-monkeypox-vaccine-live-non-replicating-prevention-smallpox-monkeypox-5061.html

4. EMA recommends approval of Spikevax for children aged 6 to 11 | European Medicines Agency [Internet]. [cited 2022 Aug 11]. Available from: https://www.ema.europa.eu/en/news/ema-recommends-approval-imvanex-prevention-monkeypox-disease

5. European Medicines Agency (EMA). Imvanex (live modified vaccinia Ankara virus) An overview of Imvanex and why it is authorised in the EU [Internet]. Vol. 44. 2022. p. 1–2. Available from: https://www.ema.europa.eu/en/documents/overview/mylotarg-epar-summary-public_en.pdf

6. Hatch GJ, Graham VA, Bewley KR, Tree JA, Dennis M, Taylor I, et al. Assessment of the Protective Effect of Imvamune and Acam2000 Vaccines against Aerosolized Monkeypox Virus in Cynomolgus Macaques. J Virol. 2013;87(14):7805–15.

7. UK Health Security Agency. Recommendations for the use of pre and post exposure vaccination during a monkeypox incident. 2022;(June). Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1080838/Recommendations-for-pre-and-post-exposure-vaccination-during-a-monkeypox-incident-6-june-2022.pdf