Mpox (MVA-BN) vaccination in pregnancy. Perspectives and challenges in data collection in remote resource-constrained settings (PregInPoxVac)

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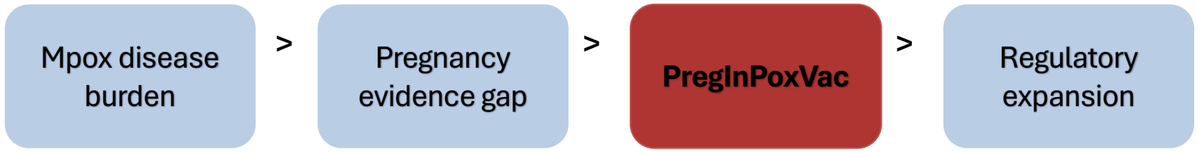
Background & Rationale

- **Mpox in pregnancy** causes severe disease, preterm birth, stillbirth, and vertical transmission.
- **Vaccination** remains off-label for pregnant and breastfeeding individuals due to the absence of clinical safety data.
- **MVA-BN** has a well-established safety profile in adults and immunocompromised individuals. A Related MVA-BN-Filo vaccine shown safe and immunogenic in pregnant individuals.
- **PregInPoxVac** will generate the first prospective maternal safety and immunogenicity data on MVA-BN, supporting label update and global vaccination policy.



PregInPoxVac Study site
General referral hospital, Boende, Tshuapa province, DRC

Area & population	19,718 km^2 · ~318,531 inhabitants
764 km	From Kinshasa Dense equatorial rainforest
Economy	Timber extraction, subsistence farming, informal trade, hunting.
Access to health	1 hospital · 33 health centres. Frequent use of traditional healers and self-medication.
Health concerns	Malnutrition, respiratory infections, STIs, **malaria**, diarrhoea, diabetes, hypertension

Clinicaltrials.gov identifier: NCT06844487
PACTR identifier: PACTR202511506487215

PregInPoxVac

Phase 3, open-label, randomised clinical trial

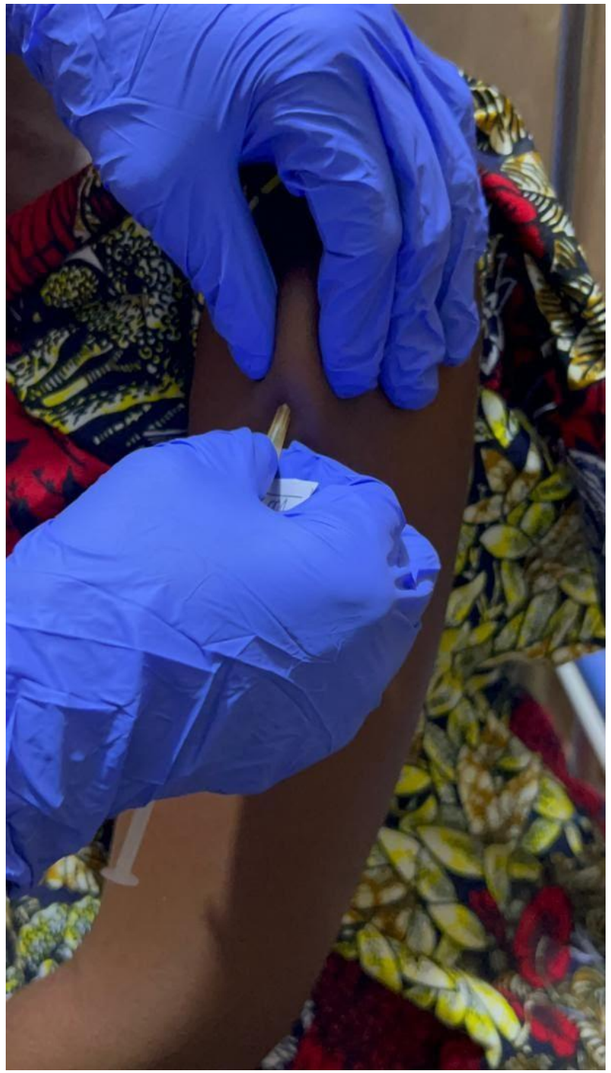
Population
Women 16–35 years old, in their second or third trimester of pregnancy (13-32 weeks of gestation)

Intervention
Two-dose MVA-BN standard regimen
Subcutaneous administration, upper arm
Day 0 and Day 28

Aims:

- Assess vaccine **safety** (maternal, infant) and **immunogenicity**

- Evaluate **maternal antibody transfer** to foetus (cord blood) and neonates (neonate serum and maternal breastmilk)



Trial Design

Maternal Group 1 (MG1)

- N=214. Enrolled and vaccinated **during pregnancy**.

Establishes direct maternal/foetal safety and immunogenicity during pregnancy

Maternal Group 2 (MG2)

- N= 148. Vaccinated during the immediate **postpartum** (<72 hours after delivery)

Serves as a safety benchmark, separating general adult side effects from pregnancy-specific adverse outcomes.

Maternal Group 3 (Post-Exposure Prophylaxis; PEP)

- N= 0

Evaluates PEP following confirmed mpox exposure.

Historical Control

The POX-MVA-045 study in DRC and Uganda (230 non-pregnant adults). Primary comparator for immunogenicity and reactogenicity

Primary Immunogenicity Objectives

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Pregnancy & Infancy mPox Vaccine study

Comparisons:	Endpoints:
 MG1 vs historical group (Adult POX-MVA-045)	**Serum** Neutralising Ab titres (GMT by PRNT) against vaccinia virus • **Timepoint**: 14 days after the second dose
IMMUNE TRANSFER STUDY	
 MG1 vs MG2	**Cord blood** Total binding & neutralising Ab against vaccinia virus, and IgG binding Ab against vaccinia & mpox viruses • **Timepoints**: Delivery **Maternal serum** IgG binding Ab against vaccinia & mpox viruses • **Timepoints**: 6 wks, 12 wks, 6 months & 13 months postpartum **Breast milk** **IgA** against vaccinia & mpox virus (LUMINEX assay) • **Timepoints**: 6 wks, 12 wks, 6 months & 13 months postpartum **IgG** against vaccinia & mpox virus (LUMINEX assay) • **Timepoints**: Delivery day, 6 wks & 12 wks **Infant serum** Total binding & neutralising Ab against vaccinia virus, and IgG binding Ab against vaccinia & mpox viruses • **Timepoints**: Delivery day, 6 wks, 12 wks & 6 months

Primary Safety Objectives

Comparisons:	Endpoints:
 MG1 vs historical group (Adult POX-MVA-045)	**Maternal. Occurrence of:** • SAE, AESI, MAAE at any time during the trial period. • Grade 3 or higher AE assessed as related to trial, until resolution of the event. • Solicited local AE (pain, swelling, pruritus, erythema, induration) after either vaccination until resolution of the event. • Solicited systemic AE (fever, nausea, vomiting, headache, fatigue, myalgia) after either vaccination until resolution of the event. • Unsolicited adverse event (UAE) after either vaccination until resolution of the event.
 MG1 vs MG2	**Neonatal/ Infant. Occurrence of :** • SAE, AESI and MAAE at any time during the trial period
 MG1 vs MG2	**Maternal/ neonatal/ Infant. Description of :** • Maternal complications, foetal outcomes (SGA/FGR, pregnancy loss), neonatal outcomes (APGAR, Finnström, neurodevelopment), infant development.

Maternal Safety Follow-up Framework

Enrolment **Antenatal care visits** **Unscheduled visits**

- Maternal medical and obstetric history
- Vaccination history, concomitant medication
- Clinical assessment: nutritional status
- Laboratory examinations, including infection screening
- Gestational age (fundal height and USG), foetal anomalies

Adverse Event (AE) collection dates

Solicited AE:

- Local and systemic events tracked for 7 days following each dose

Unsolicited AE:

- Tracked for 28 days following each dose

Based on FDA Toxicity Grading Scale and Brighton Collaboration

Serious AE, Medically Attended AE, and AE of Special Interest.

- Monitored from the time of enrolment until 13 months after delivery

Based on SPEAC guidelines.

Maternal Safety Follow-up Framework

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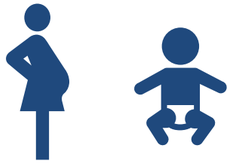
Birth

- Antenatal bleeding
- Spontaneous abortion
- Mode of delivery
- Dysfunctional labor
- Infection
- Hypertensive disorders
- Maternal death
- Postpartum haemorrhage

- APGAR scores
- Birth weight
- Age at birth (Finnstrom score)
- Perinatal/neonatal death
- Congenital anomalies
- Neonatal infections

Follow-up visits



- Vaccination history, concomitant medication
- Clinical assessment: nutritional status, infant growth and development

Serious AE, Medically Attended AE, and AE of Special Interest.

- Based on SPEAC guidelines.
- Monitored from the time of enrolment until 13 months after delivery

Current Project Status

Started June 2025 • Updated May 29, 2026

Total enrolled across maternal groups:
- 362/362

First dose vaccinated:
- **MG1:** 214/214
- **MG2:** 111/148

Second dose vaccinated:
- **MG1:** 207 /214
- **MG2:** 102/148

Delivery & Infant Follow-up
- **MG1:** 187/214
- **MG2:** 119/148

DSMB Oversight
- **3** Sessions completed, trial approved to continue

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Setting the Scene: Data Collection in Boende

A Remote and Underserved Environment

The PregInPoxVac study is conducted in a remote forested area of the DRC with significant structural constraints:

- Limited road infrastructure and difficult transportation
- Unstable or absent internet connectivity
- No reliable power supply for digital tools

These realities shaped every aspect of how data was collected, managed, and verified throughout the study.

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Maternal Healthcare Access in the Field

Barriers to Routine Antenatal Care

From a maternal health perspective, the local healthcare landscape posed direct challenges to participant follow-up:

- Many women did not attend regular antenatal consultations
- Home deliveries remained widespread and common
- Geographic dispersal made timely data collection difficult

These gaps required the research team to adapt standard protocols to a highly fluid and unpredictable participant population.

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Sociocultural Barriers to Research Participation Participation

Fear of Blood Collection

Some participants feared sample collection, with misconceptions that blood could be used for mystical purposes or sold abroad.

Rumors and Witchcraft Beliefs

Rumors linking the study to witchcraft circulated in certain communities, fueling hesitancy and withdrawal.

Mistrust of Vaccines and Foreign Research

Broader skepticism toward vaccines, clinical research, and foreign-led studies created persistent trust barriers.

Alternative Healthcare Preferences

Some women prioritized prayer churches over formal hospital care, delaying enrollment and follow-up visits.

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Follow-up and Data Management Hurdles

Participant Tracking

Maintaining consistent follow-up across a mobile population is one of the most demanding aspects of the study:

- Women returned to remote villages after delivery
- Missed visits and location changes occurred without notice
- No reliable contact information for many participants

REDCap Tool Refinement

Throughout the study, REDCap forms and data collection instruments have been progressively refined. While necessary for quality, these iterative updates:

- Required ongoing retraining of site staff
- Added coordination complexity for field teams
- Contributed to increased operational workload overall

⚠ Operational adaptability is not optional — it is a core competency required of every team member throughout the study.

How the Team Responded

Mobile Tracing Teams

Active participant tracing through mobile field teams reduced loss to follow-up significantly.

Community Engagement

Local leaders, churches, and traditional birth attendants were engaged to build trust and ease enrollment.

Night-Duty System

A dedicated night-duty rotation improved emergency maternal follow-up and reduced missed data capture.

Lessons Learned from PregInPoxVac

High-quality maternal clinical research *can* successfully be conducted in rural African settings — but it demands flexibility, community trust, and deep local adaptation.

Beyond Logistics

Data collection challenges in remote settings are not only technical — sociocultural dimensions are equally critical to address.

Trust as Infrastructure

Community relationships and earned trust proved to be as essential as any digital tool or study protocol.

A Replicable Model

The adaptive strategies developed in Boende offer a practical framework for future field research in similar settings.

Matondo — Thank You

With deep gratitude to the entire PregInPoxVac field team, the community of Boende, and all participating families.

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