

# Phase 3 Infant Safety & Immunogenicity Trial of MVA-BN® in DRC

NCT06844487

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 3
<b>Sponsor</b>	Jean-Pierre Van geertruyden
<b>Enrollment</b>	344 participants

## Key Eligibility Criteria

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### Inclusion (10)

- The participant must be between 4 and 24 months old upon enrolment.
  - The participant's parent or legal guardian must pass (e9/10) the TOU after being advised of the risks and benefits of the trial in a language understood by the parent/guardian and before performing any trial-specific procedures.
  - \- Note: If the participant's parent or guardian fails the TOU test on the first attempt, he/she must be retrained on the purpose of the study and must take the test again (2 repeats are allowed). If the participant's parent/guardian fails on the third attempt, the screening or consenting procedures should not continue.
  - The participant's parent or guardian must sign and date the informed consent form after reading the form and being advised of the risks and benefits of the trial in a language understood by the participant and before performing any trial-specific procedures.
  - The participant must live in the Boende health zone or its surrounding health zones in the Tshuapa province of the DRC.
- ... and 5 more (see full listing online)

### Exclusion (23)

- The child is excluded if their mother received the MVA-BN vaccine during her pregnancy with the child or during the immediate postpartum period while breastfeeding the child.
  - Known history of cowpox, mpox or vaccinia infection.
  - Close contact in the 2 weeks prior to signing the ICF with anyone known to have mpox.
  - Known history of or active autoimmune disease (vitiligo or thyroid disease requiring thyroid replacement are not exclusions), history of Guillain-Barré syndrome or Reye's syndrome.
  - Having received any smallpox or licensed or investigational poxvirus-based (e.g. ACAM2000, MVA-BN based like MVA-BN-Filo) vaccine in the past.
- ... and 18 more (see full listing online)

## Locations (1 total)

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Boende Hôpital Général de Référence, Boende, Boende, La Tshuapa, Democratic Republic of the Congo