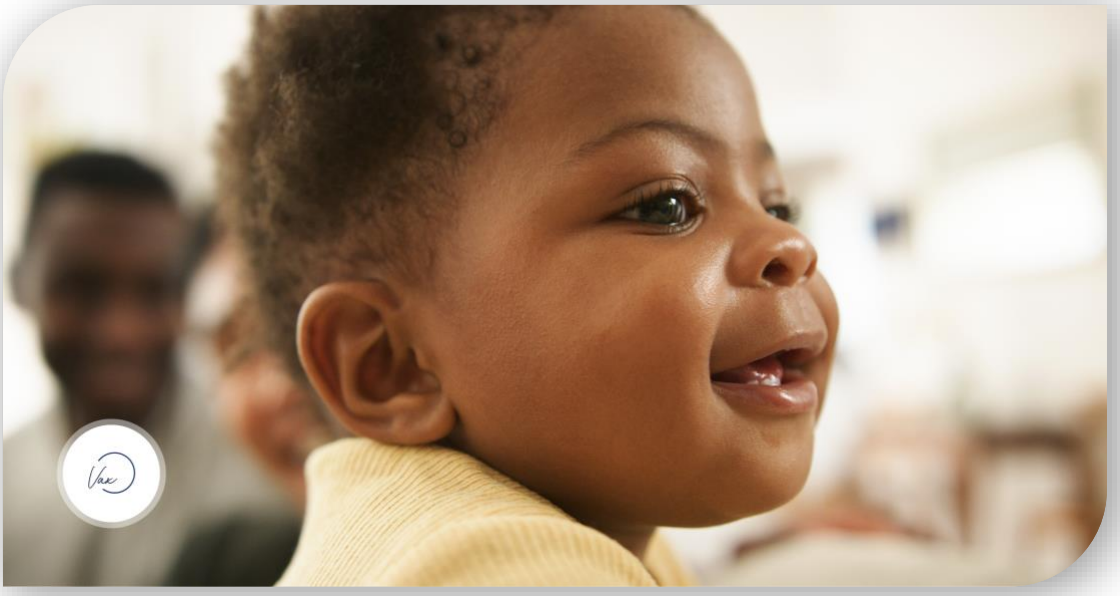
Nigeria 3-Phase MAP Vaccine Roadmap 2025–2030

A Scalable Model for Equitable Vaccine Access and Local Production



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About LunaVax

Across Africa, millions of children and families still face barriers to essential vaccines, leaving communities vulnerable to preventable diseases and future outbreaks.

LunaVax was founded to change this reality. Our mission is to deliver innovative, accessible, and locally produced vaccines, ensuring that no one is left behind**.**

We're advancing that mission through the LunaChain, an integrated vaccine access network designed to connect new tools, delivery models, and data systems into one ecosystem.

LunaChain = Tools + Delivery Models + Data → Equitable Vaccine Access

The MAP vaccine pilot is the first layer of that mission, a foundational step to reimagine how vaccines are delivered, tracked, and trusted across Nigeria and beyond.

Together, we can make vaccine equity a reality.

Executive Summary

Every year, more than 2 million Nigerian children miss essential vaccinations, leaving them vulnerable to preventable diseases and deepening health inequities. Traditional vaccine delivery systems continue to face persistent challenges, including cold chain limitations, needle hesitancy, and weak accountability structures.

To address these challenges, LunaVax is developing one of the world's first Phase III MAP study frameworks through the Harvard Medical School GCSRT program and leading the pre-implementation phase for one of Africa's first MAP-and-biometrics vaccine delivery models. The pilot will focus on the measles–rubella vaccine, aligning with WHO/PDVAC guidance and the global MR-MAP development pathway**.**

This initiative will evaluate a scalable, equity-driven model that:

- Simplifies vaccine delivery through needle-free, thermostable MAPs
- Strengthens accountability using biometric tools for dose tracking and verification
- Builds policy-ready evidence to support national integration and lay the foundation for future local vaccine production

Global health partners including Gavi, WHO, UNICEF, the Gates Foundation, and PATH have prioritized MAPs for LMICs, yet progress remains limited by the absence of pilot-scale production capacity. LunaVax addresses this gap by co-developing a small-scale, GMP-compliant production line alongside the pilot program, ensuring that field evidence and production readiness advance together**.**

The Phase I implementation will engage sites in Lagos, Abuja (FCT), Adamawa, and Anambra**,** enabling insights across both major urban hubs and rural last-mile settings to guide equitable delivery, accountability, and system strengthening.

If successful, this model could offer a scalable blueprint for expanding access to routine childhood vaccines across the continent.

Abbreviations

AE – Adverse Event

AMC – Advance Market Commitment

APC – Advance Purchase Commitment

AVAREF – African Vaccine Regulatory Forum

BARDA – Biomedical Advanced Research and Development Authority

CAPEX – Capital Expenditure

CEPI – Coalition for Epidemic Preparedness Innovations

CQAs – Critical Quality Attributes

CRF – Case Report Form

cGMP – Current Good Manufacturing Practice

CTC – Controlled Temperature Chain

ECVP – Evidence Considerations for Vaccine Policy (WHO)

EDC – Electronic Data Capture

EOSL – End of Shelf Life

FCT – Federal Capital Territory

FMoH – Federal Ministry of Health

Gavi – Gavi, the Vaccine Alliance

GCP – Good Clinical Practice

GCSRT – Global Clinical Scholars Research Training

GHS – Ghana Health Service

GMC – Geometric Mean Concentration

GMP – Good Manufacturing Practice

HPV – Human Papillomavirus

ID – Identification

IFU – Instructions for Use

IRB – Institutional Review Board

LMICs – Low- and Middle-Income Countries

MAP – Microarray Patch (microneedle patch)

MBA – Multiplex Bead Assay

mRNA – Messenger Ribonucleic Acid

MR – Measles–Rubella

MR-MAP – Measles–Rubella Microarray Patch

MR-SC – Measles–Rubella (subcutaneous injection)

MRL – Manufacturing Readiness Level

NAFDAC – National Agency for Food and Drug Administration and Control

NI – Non-Inferiority

NHREC – National Health Research Ethics Committee

NPHCDA – National Primary Health Care Development Agency

NRA – National Regulatory Authority

OPEX – Operational Expenditure

PDVAC – Product Development for Vaccines Advisory Committee

PoC – Proof of Concept

PQ – (WHO) Prequalification

QMS – Quality Management System

R&D – Research and Development

SAE – Serious Adverse Event

SAGE – Strategic Advisory Group of Experts on Immunization

SIA – Supplemental Immunization Activity

SNA – Serum Neutralization Assay

SOP – Standard Operating Procedure

Stata – Statistical software

TRL – Technology Readiness Level

TRIPS – Trade-Related Aspects of Intellectual Property Rights

TRS – Technical Report Series (WHO)

UNICEF – United Nations Children's Fund

URS – User Requirements Specification

VIPS – Vaccine Innovation Prioritization Strategy

VVM – Vaccine Vial Monitor

VVM30 – Vaccine Vial Monitor, Category 30 (highest heat-stability class; supports CTC labeling/use cases)

WHO – World Health Organization

WLA – WHO-Listed Authority

WUENIC – WHO/UNICEF Estimates of National Immunization Coverage

WTO – World Trade Organization

YF – Yellow Fever

saRNA – Self-amplifying Ribonucleic Acid

Global Immunization Landscape, 2021

Despite decades of progress, millions of children around the world still miss out on life-saving vaccines. As illustrated below, Nigeria remains one of the top countries with zero-dose children, highlighting the urgent need for innovative delivery approaches like MAPs and integrated vaccine access networks.

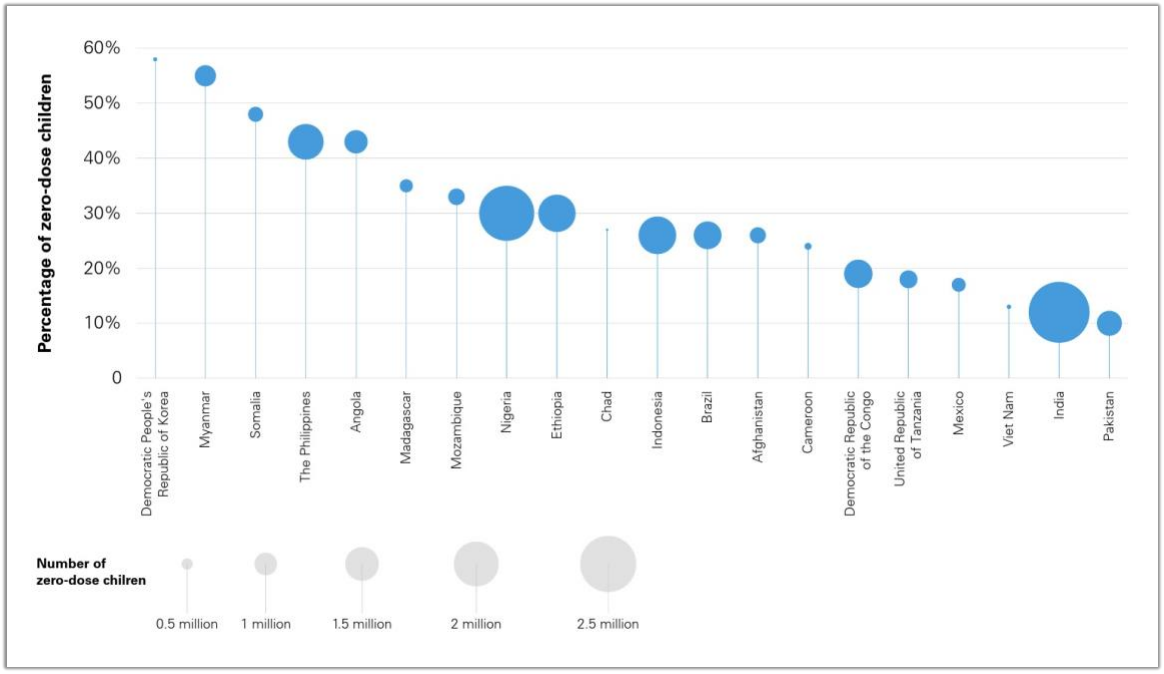

Figure 1. Top 20 countries with the largest numbers of zero-dose children.

***Source**: World Health Organization (WHO) and United Nations Children's Fund (UNICEF), "Estimates of National Immunization Coverage (WUENIC), 2021 revision," July 2022.*

Background & Rationale

Nigeria faces one of the world's most persistent immunization coverage gaps, with millions of children under-immunized, particularly in rural and underserved communities. Addressing this challenge requires new delivery models that combine innovation with system-level integration.

Key barriers include:

- Cold chain limitations - Infrastructure constraints make it difficult to maintain vaccine potency in remote areas.
- Needle hesitancy - Caregivers' fear of injections often leads to missed appointments or low uptake of vaccination services.
- Accountability gaps - Limited data and identity systems hinder dose tracking and follow-up.

MAPs and biometric verification together offer a practical and scalable solution. MAPs can be stored and used without strict cold chain requirements and have shown strong potential to improve caregiver acceptability while requiring minimally trained personnel. Biometric tools ensure that every dose is accurately recorded and linked to the correct recipient, strengthening immunization records and enabling access for populations without formal identification.

This pilot goes beyond logistics. It aims to establish a scalable, locally driven model that supports Nigeria's health system goals and lays the foundation for broader vaccine delivery capacity across the continent. It is the first step in LunaVax's long-term strategy to build the *LunaChain*, a connected vaccine delivery network that integrates new tools, delivery models, and data systems to close access gaps from lab to last mile. The MAP vaccine pilot serves as the foundation of this system, generating the evidence needed to scale future layers such as mobile delivery, real-time logistics, and local production.

Local Production Readiness:

While MAPs and biometric systems solve many delivery and accountability challenges, their global rollout ultimately depends on one critical factor: production capacity.

- Advancing beyond early trials requires a pilot-scale production line that meets Good Manufacturing Practice (GMP) standards. Without this facility in place, MAP products cannot progress to large-scale clinical testing, regulatory approval, or routine use.
- A pilot production line, typically semi-automated, is designed to produce 10 to 15 million patches per year. It provides the foundation for safe, consistent, and cost-effective production by validating sterility processes, quality controls, production workflows, and cost benchmarks at scale.
- Investing early in production capacity, even before trials are complete, can accelerate approval and emergency use. Waiting until all vaccines are proven could delay MAP access by many years, possibly into the 2030s.
- Facilities should be designed for flexibility (able to produce different vaccines and MAP formats) and distributed across multiple regions to strengthen supply security, expand access, and enable rapid response to future outbreaks.

This reality highlights the strategic importance of pairing field evidence with production readiness, a combined focus that will enable Nigeria not only to deploy MAP technology but also to become a continental leader in its production**.**

Local pilot manufacturing will be designed to meet WHO Technical Report Series expectations for lot-to-lot consistency and end-of-shelf-life performance, with a view to eventual technology transfer to Nigerian facilities.

Phase III activities will target VVM30/CTC-ready labeling to enable controlled-temperature outreach and will include planning for three consecutive GMP lots to support consistency and PQ requirements (subject to partner and NRA agreement).

MAP + Biometrics Innovation

MAPs

MAPs use dissolvable micro-projections to deliver vaccines through the skin, eliminating needles, simplifying administration, and reducing the need for trained healthcare workers. They offer improved stability at higher temperatures and are easily transported, making them suitable for use in clinics, community outreach programs, school-based immunization campaigns, and last-mile delivery settings.

Biometric Verification

Biometric identity tools, such as fingerprint and facial recognition scanners, enable precise dose verification, improved record-keeping, and better follow-up, particularly among populations without formal ID systems.

Combined Potential

Together, MAPs and biometrics help address three persistent challenges in immunization delivery:

1. Cold chain and logistics - by enabling easier transport and storage
2. Needle hesitancy - by improving acceptability among caregivers
3. Accountability - by ensuring accurate dose tracking, strengthening data systems, and improving follow-up

Combining MAPs with biometric verification helps address key delivery challenges, including last-mile logistics, usability, and accountability. The pilot will also provide the human-factors and acceptability evidence required for regulatory approval of a combined vaccine-and-device product.

Potential added benefits, including dose-sparing and improved heat stability, will be explored during the study and reported based on generated evidence**.**

Mission & Objectives

Mission

To develop a scalable, evidence-based model that integrates MAP delivery and biometric verification into Nigeria's immunization system, paving the way for local manufacturing and continental leadership in vaccine innovation.

Objectives

1. Demonstrate the feasibility, usability, and acceptability of MAP delivery in real-world Nigerian contexts.
2. Evaluate biometric verification as a tool for strengthening accountability and dose tracking.
3. Generate evidence to inform policy adoption at both state and national levels.
4. Build strategic partnerships to transition from feasibility to policy integration and local production.
5. Define critical quality attributes (CQAs) and human-factors requirements for MAP use in Nigerian settings and align these with emerging regulatory expectations for vaccine–device combination products.
6. Build a pilot-manufacturing coalition and investment pathway (cost-share, push/pull incentives) toward GMP pilot capacity (10–15M doses/year) aligned with Nigeria's 2028 self-reliance goals.

Alignment with Nigeria's Vaccine Policy, (2021)

POLICY FOCUS: Advancing local manufacturing through innovation, self-sufficiency, and WTO TRIPS flexibilities (including patent waivers).

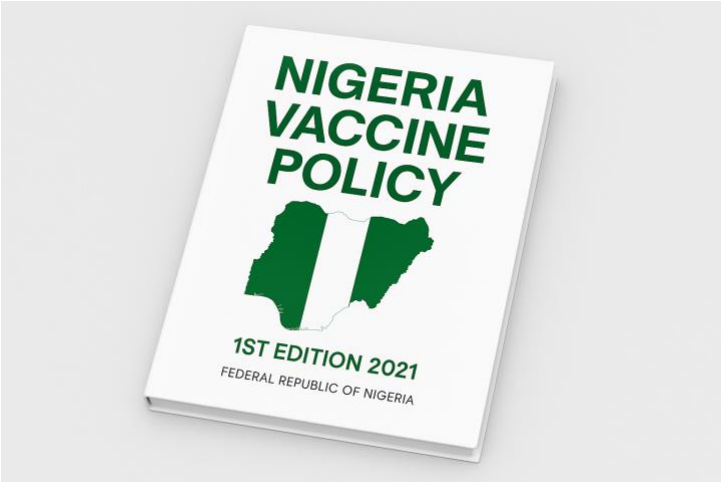

Figure 2. Nigeria's Vaccine Policy (2021), highlighting national goals for innovation, equitable access, and local vaccine production.

This pilot directly supports the priorities outlined in Nigeria's Vaccine Policy (2021), which emphasizes innovation, equitable access, and vaccine self-sufficiency. By generating the evidence, partnerships, and system foundations needed to enable future domestic production, it helps translate these policy goals into action.

All activities are subject to approvals from Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), AVAREF-aligned processes as applicable, and national ethics oversight (NHREC/IRBs).

As Nigeria transitions toward full domestic financing and ownership of vaccine procurement and distribution by 2028, pilots like this will be key to shaping scalable, locally driven delivery models that strengthen future manufacturing and supply systems.

The planned introduction of active MAPs in Phase III of this pilot represents a critical step in this process, generating operational data on delivery performance and system readiness to guide national scale-up and long-term integration into routine immunization.

3-Phase Roadmap

Table 1. Overview of the three implementation phases of the MAP vaccine roadmap (2025–2030), highlighting timelines, geographic scope, sample size, and key objectives for each stage.

Phase	Timeline	States	Sample Size	Key Focus	Outputs
Phase I Pilot	Oct 2025 – Dec 2026	Lagos, Abuja, Adamawa, Anambra (4 total)	1,200 caregivers (300/state)	Usability, acceptability, human-factors validation, and biometric match rate (ID linkage success)	Feasibility report; human-factors/acceptability dossiers; biometric match-rate analysis with data dictionary; draft CQA list + test methods (v0.1); SOPs for MAP application and biometric workflow; initial regulator engagement notes (combo-product pathway/ethics).
Phase II Pilot	Jan 2027 – Jun 2028	Capacity scale-up within the 4 states	+800 caregivers (2,000 total)	Cost, logistics, and system performance evaluation; subgroup analysis; policy engagement; pilot-manufacturing planning	Cost-effectiveness analysis; logistics/throughput insights report (urban, rural, outreach); subgroup findings; policy briefs and stakeholder minutes; sterility approach & validation plan (concept of controls); coating/drying process maps; preliminary TRL/MRL

					assessment; pilot-line coalition MoU + URS outline.
Phase III Clinical Trial	Jul 2028 – Jun 2030	+6 states added (10 total)	+3,000 caregivers (5,000 total)	Introduction of active MAPs; workforce capacity building; national integration; regulatory engagement and evidence generation for PQ/licensure; outbreak-response deployment planning	Live-MAP performance dataset (safety, SRR/GMC, usability); workforce training curriculum + reports; evidence for policy and integration; lot-to-lot/consistency summary (per partner plan); VVM30/CTC thermostability package; regulatory submissions & roadmap (NAFDAC/WLA/WHO PQ modules); pilot-line business case (capex/opex; 10–15M/yr scenarios); AMC/APC concept note; emergency-use readiness playbook; MAP outbreak-response framework

***Note**: Timelines are estimated and will be refined through regulatory consultations and partner planning. Phases I–II represent LunaVax-led feasibility and readiness activities; Phase III is the main clinical trial whose protocol and regulatory package are being developed under the Harvard GCSRT program. Phase III execution will proceed post-program subject to supply, ethics, and funding availability.*

Expected Outcomes & Impact

1. Expanded Immunization Coverage
By simplifying delivery through needle-free MAPs and reducing cold chain dependency, the pilot will extend vaccination services to underserved and last-mile communities. Improved geographic reach will help close persistent immunization gaps and ensure that children in remote areas receive life-saving protection.

2. Stronger Accountability Systems
Biometric dose verification will enhance the accuracy of immunization records, reduce duplication, and enable better follow-up for missed doses. These improvements will help establish a more reliable, data-driven foundation for vaccine delivery and policy decision-making.

3. Validation of New Delivery Models
During Phase III, active MAP deployment will provide field-validated evidence of performance, safety, and operational readiness. These insights will guide large-scale adoption and position Nigeria to transition from donor dependence to self-sustained vaccine delivery.

4. Evidence for Policy and Scale-Up
The pilot will generate real-world evidence on usability, cost-effectiveness, and operational feasibility to inform national immunization strategies. This evidence base will support policy adoption at both state and federal levels and guide the integration of MAP-based delivery models into routine programs.

5. Establishment of Proof of Concept
Results from Phases I and II will establish proof of concept for the combined MAP and biometric delivery model, generating the evidence base required for large-scale adoption, policy integration, and future Transition-to-Scale investment.

6. Pathway to Local Production and Self-Sufficiency
Findings from the pilot will inform regulatory engagement, technical requirements, and strategic partnerships necessary to enable local MAP production, beginning with formulation, coating, and final assembly capacity as an initial step. This work will directly support Nigeria's vaccine self-reliance agenda and broader continental manufacturing goals.

7. Manufacturing Readiness & Emergency Preparedness

A documented path to GMP pilot-scale production (target 10–15M patches/year) including sterility strategy, CQAs, and indicative costs, supporting emergency-use listing preparedness**,** stockpile concepts, and future scale-out to additional states/regions.

WHO Prequalification & Regulatory Pathway

LunaVax's three-phase roadmap is aligned with WHO/PDVAC guidance for measles–rubella microarray patches (MR-MAPs). Phases I–II are implementation/feasibility stages that generate human-factors, usability, workflow, and system-readiness evidence for a combined MAP + biometrics model. Phase III is the confirmatory clinical trial stage with live MAPs to support regulatory licensure, WHO prequalification (PQ), and programmatic use.

Confirmatory Phase III design (high level)

- Population & comparator: 9–10-month MR-naïve infants, randomized 1:1 to MR-MAP vs subcutaneous MR (MR-SC).
- Primary endpoints: Non-inferiority (NI) immunogenicity and safety assessed 6 weeks after the first dose**.**
- Second dose (subset, descriptive): A subset receives a second MR dose at +6 months (same or alternate presentation) with a descriptive immunogenicity readout 6 weeks post-dose 2**.**
- Safety follow-up: Serious adverse events tracked to 6 months post-final dose in accordance with WHO guidance.
- Thermostability & labeling targets: Package supports VVM30 and CTC use cases to enable outreach and SIAs, subject to data.

Regulatory/PQ alignment and critical path

- Pre-Phase III consultations: End-of-Phase II / pre-Phase III engagement with the target National Regulatory Authority (NRA) (preferably a WHO-Listed Authority**)** and the WHO PQ team, to confirm: NI endpoints (SRR/GMC), NI margin, analysis sets, safety follow-up, and acceptability of a descriptive second-dose subset.
- CMC & device readiness**:** Prior to trial start, confirm GMP clinical supply, validated potency/assays, and three consecutive MR-MAP drug-product lots with aligned shelf-life specifications and thermostability plans; device human-factors files and IFU aligned to combo-product expectations.
- Lot-to-lot & EOSL considerations**:** Demonstrate analytical/CMC lot consistency pre-trial; include three production lots in the pivotal study to ensure

representativeness. Perform stability testing consistent with WHO TRS and target labeling claims.

- Co-administration & special populations**:** To preserve timelines, evaluate potential co-administration (e.g., YF, polio) and special populations (malnutrition, HIV+) in separate or parallel studies (pre- or post-licensure) per NRA/WHO advice.
- Policy pathway**:** Align with WHO Evidence Considerations for Vaccine Policy (ECVP) and SAGE processes early; pair clinical results with implementation data from Phases I–II to inform programmatic recommendations.

Projected Phase III timeline

- The design targets a primary NI readout 6 weeks after completion of enrollment**,** with a descriptive subset readout 6 weeks after the second dose at +6 months**,** and SAE follow-up to 6 months post-final dose**.**
- A 24-month confirmatory window is plausible but contingent on: pre-agreed endpoints/margins with NRA/WHO PQ, timely ethics/import approvals, ready GMP clinical supply, validated immunogenicity assays (SNA or validated MBA), and efficient multi-site enrollment and lab throughput.

Access & sourcing for Phase III

- Access to antigens and devices will be pursued via memoranda of understanding (MoUs) with developers and is contingent on NRA/WHO alignment, country ethics approvals, and supply availability**.**

Partnership model

LunaVax will partner with MR-MAP developers/manufacturers to:

- Incorporate non-inferiority immunogenicity endpoints vs MR-SC
- Document manufacturing consistency across consecutive GMP lots
- Meet VVM30/CTC thermostability targets; and
- Embed implementation research on priority use cases (outreach/SIAs, zero-dose).

Funding Priorities

To move from feasibility to full implementation, LunaVax seeks partners to co-invest in field evidence and local production readiness, key steps to accelerate access.

We are engaging funding partners committed to innovation, equity, and long-term health system strengthening across implementation, technology integration, data systems, and policy alignment.

Key funding priorities include:

- Capacity building of the local workforce for sustainable delivery
- Procurement and distribution of MAP prototype patches
- Biometric hardware, system integration, and technical training
- Community mobilization and health worker engagement
- Field implementation, logistics, and supervision
- Independent monitoring, data collection, and analysis
- Regulatory engagement and policy integration
- Pilot-line coalition design + costing (capex/opex model for 10–15M patches/year; site options, single- vs multi-format trade-offs).
- De-risking instruments (push grants and pull mechanisms like Advance Market Commitment/Advance Purchase Commitments**)** to enable at-risk manufacturing alongside Phase I–II work.

LunaVax is finalizing detailed cost estimates with implementation and academic collaborators and welcomes co-investment in this pilot phase and its continued development and impact.

Partnership Opportunities

LunaVax views this pilot as the first step in a broader journey toward vaccine equity, resilient health systems, and regional self-sufficiency. Strong partnerships from antigen and device developers to regulatory and manufacturing collaborators will be essential to scale implementation and integrate MAP delivery into national systems.

Partnership opportunities include:

- Technical partners to support study design, field implementation, and data analysis
- Funding partners to invest in a scalable, high-impact innovation
- Implementation and logistics partners to design and manage distribution models and last-mile delivery systems that leverage MAPs' thermostable advantages
- Health facility and clinical partners to lead caregiver enrollment, integrate MAP delivery into routine services, and provide operational feedback from the field
- Digital and data partners to advance biometric integration, real-time monitoring, and program performance analytics
- Policy and advocacy partners, including those interested in joining the Luna360 global advocacy network, to align pilot outcomes with national immunization strategies, support public awareness efforts, and accelerate policy adoption
- Industry partners to support the establishment of local MAP formulation and final assembly capacity, creating a pathway toward domestic production
- Regulatory science partners (combo-product pathway, sterility, CQA harmonization; Microneedle Regulatory Working Group engagement).
- Manufacturing & equipment partners (coating, drying, mold production; high-speed line suppliers) to prepare pilot-line URS and validation plan.
- Global de-risking partners (CEPI/BARDA-style funders; VIPS-aligned orgs) to structure push/pull financing and AMC/APC pilots.

Together, we can turn today's pilot into tomorrow's model for equitable vaccine access across Africa.

Data & Evidence

Overview

Robust evidence generation is central to the MAP pilot, not only to validate feasibility in real-world settings, but also to produce the operational, clinical, and economic insights needed to shape national policy, inform scale-up decisions, and guide future pathways for local vaccine production.

This section outlines the methodologies that will ensure high-quality data collection across user experience, system performance, cost, and policy readiness.

Ethics & Local Engagement

All study activities will adhere to national and international ethical standards. NHREC and Institutional Review Board (IRB) approvals will be obtained prior to initiation, with caregiver consent and assent workflows implemented in all participating sites. Adverse events (AEs) and serious adverse events (SAEs) will be reported in accordance with Good Clinical Practice (GCP). Community advisory groups will be established in participating states to support transparency, engagement, and local trust.

1. **User Experience and Acceptability**

   These tools will evaluate how caregivers and health workers interact with MAP technology, generating critical insights into usability, adoption barriers, and frontline realities that will shape scale-up strategies.

   - **Structured Caregiver Surveys**
     Assess perceptions, comfort, and acceptability of MAP delivery, as well as behavioral drivers influencing participation and follow-up.
   - **Health Worker Interviews**
     Capture qualitative feedback on workflow integration, ease of use, and perceived operational strengths and challenges.

2. **Clinical and Operational Performance**

   Phase III will use non-inferiority immunogenicity endpoints (e.g., SRR/GMC) versus subcutaneous MR, with safety follow-up consistent with WHO guidance. Selected concomitant vaccine sub-studies (e.g., YF, polio) may be included per NRA/WHO PQ

consultation. Clinical and operational data will assess readiness and safety across diverse settings to inform scale-up.

- **Case Report Forms (CRFs)**
  Digitally implemented via the Electronic Data Capture (EDC) platform to capture participant-level data, including biometric enrollment, MAP application observations, and any adverse events.
- **EDC Platform**
  Enables secure offline data entry, real-time validation checks, and centralized oversight.
- **Biometric System Analytics**
  Analyze fingerprint and facial data to assess enrollment accuracy, dose linkage, and data integrity.
- **Statistical Analysis**
  Quantitative data will be exported into statistical software such as Stata for descriptive and inferential analysis, enabling robust evaluation of outcomes including usability, biometric match rates, operational efficiency, and cost-effectiveness.
- **Sterility & Bioburden Controls (planning)**
  Define approach for cleanroom classification, environmental monitoring, and in-process controls relevant to MAP manufacturing.
- **CQA Development**
  Draft and iterate critical quality attributes (drug content uniformity, tip-loading for coated MAPs, dissolution time for dissolving MAPs, mechanical strength, residual moisture) with associated test methods.
- **Human-Factors/Use-Error Evaluation**
  Standardized task analyses and simulated-use assessments to inform labeling, instructions, and training.

3. System Performance and Readiness

Operational tools will assess logistics, scalability, and cost-effectiveness to guide large-scale implementation.

- **Operational Performance Metrics**
  Track delivery timeliness, distribution efficiency, enrollment rates, biometric verification success, and session completion rate.

- **Cost and Resource Analysis**
  Estimate per-dose and per-site costs, informing cost-effectiveness analyses and scale-up planning.
- **Manufacturing Readiness Metrics**
  MRL/TRL tracking, yield assumptions, takt-time estimates, and throughput scenarios for a pilot line (10–15M/year).
- **Community Engagement Insights**
  Measure levels of awareness, trust, and participation, providing actionable data for communication strategies.
- **Emergency-Use Framework Inputs**
  Triggers, regulatory pre-submission checklist, and stockpile packaging/labeling options suitable for decentralized deployment.

4. Data Quality Monitoring

High-quality data will support regulatory submissions, policy engagement, and future expansion.

- **Data Quality Assurance Systems**
  Automated validation checks, daily sync logs, supervisor back-checks, and de-identified audit trails will ensure data integrity and adherence to Good Clinical Practice (GCP) standards.
- **Real-Time Dashboards and Analytics**
  Deliver continuous visibility into field operations, logistics performance, and biometric data accuracy to enable rapid, evidence-based decision-making.
- **Biometrics Data Protection**
  Consent workflows, data minimization, encryption in transit/at rest, and de-identification aligned with the Nigeria Data Protection Act and WHO digital health guidance.

***Note**: Final data collection platforms, configurations, and data flows will be validated in collaboration with Harvard GCSRT program faculty during the initial design phase, and any resulting updates will be incorporated into the full study protocol.*

Beyond the Pilot

Transforming Vaccine Access in Africa and Beyond

This effort goes beyond MAPs and biometric tools. By advancing next-generation vaccine platforms including mRNA, saRNA, and protein subunit technologies alongside initiatives such as mobile clinics and drone delivery, we are laying the groundwork for a new immunization ecosystem designed for the realities of low- and middle-income countries, one that not only closes today's access gaps but also strengthens preparedness for future outbreaks.

To strengthen outbreak readiness, we will also explore establishing a strategic MAP reserve (pending regulatory pathways). The regional manufacturing approach is intended to reduce reliance on imports and prevent the supply disruptions experienced during COVID-19.

While this pilot focuses on the measles-rubella vaccine patch as the first application, the MAP delivery platform is being designed to allow future inclusion of additional vaccines as evidence, partners, and regulatory alignment progress**.**

As we transition into implementation, LunaVax will continue to work closely with government partners, global health agencies, mission-aligned funders, and industry collaborators to ensure that the insights from this pilot translate into lasting impact.

The success of this effort depends on collective action.
By aligning expertise, resources, and commitment, we can turn today's pilot into tomorrow's standard and bring equitable vaccine access closer to every community.

Appendix

1. Appendix A — Pilot Line Concept (Summary)

• Annual capacity: 10–15M MAPs/year (semi-automated).

• Key processes: MAP coating or molding, inspection, packaging, labeling, quality management, and sterility controls.

• Key outputs: Small trial-ready batches for consistency testing, regulatory documentation, and scale-up planning.

All pilot-line parameters will be refined during URS development and vendor engagement; validation and performance qualification will follow cGMP and relevant WHO TRS guidance.

2. Appendix B — Financing & Partnership Model

• Upfront support**:** Grants for equipment setup, validation, and workforce training.

• Commitments**:** AMC/APC-style agreements tied to volume and affordability post–proof of concept.

• Partnership model: Alignment with VIPS partners and collaboration with Nigeria federal/state stakeholders to support sustainable scale.

3. Appendix C — Table 2. Two Pilot-Facility Options

Option	Description	Advantages	Considerations
Single-Format Line	Dedicated to one MAP type (e.g., dissolving or coated)	Faster setup, simpler validation, lower initial cost	Less flexibility if new vaccines or formats emerge
Multi-Format Line	Capable of switching between MAP types	Greater flexibility, long-term adaptability, broader product pipeline	Higher capex/opex, longer validation timeline

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From Innovation to Immunity

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