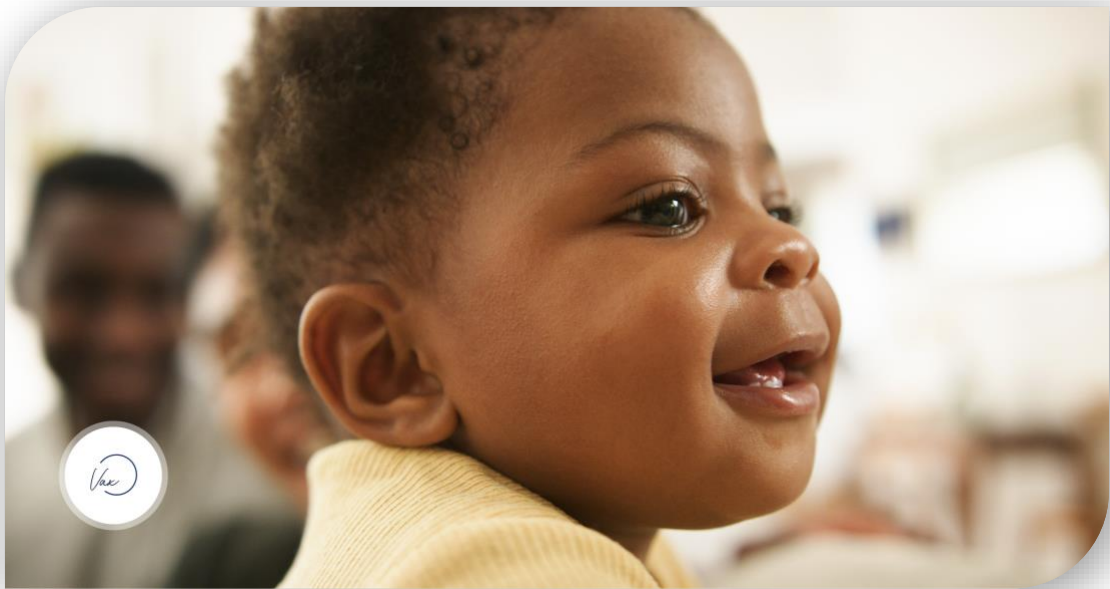


Nigeria 3-Phase MAP Vaccine Roadmap 2025–2030

A Scalable Model for Equitable Vaccine Access
and Local Production



October 2025

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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, through the Harvard Medical School GCSRT program, is leading Africa's first pilot combining microneedle vaccine patches (MAPs) with biometric verification, pioneering a new model for vaccine delivery.

This pilot 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

By generating real-world data beginning with phase I of this 3-Phase MAP vaccine pilot, conducted across four diverse states including Lagos, Abuja (FCT), Adamawa, and Anambra that reflects both major urban centers and rural last-mile areas, this initiative aims to advance a next-generation delivery model that combines equitable access, digital accountability, and system-wide readiness.

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

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.

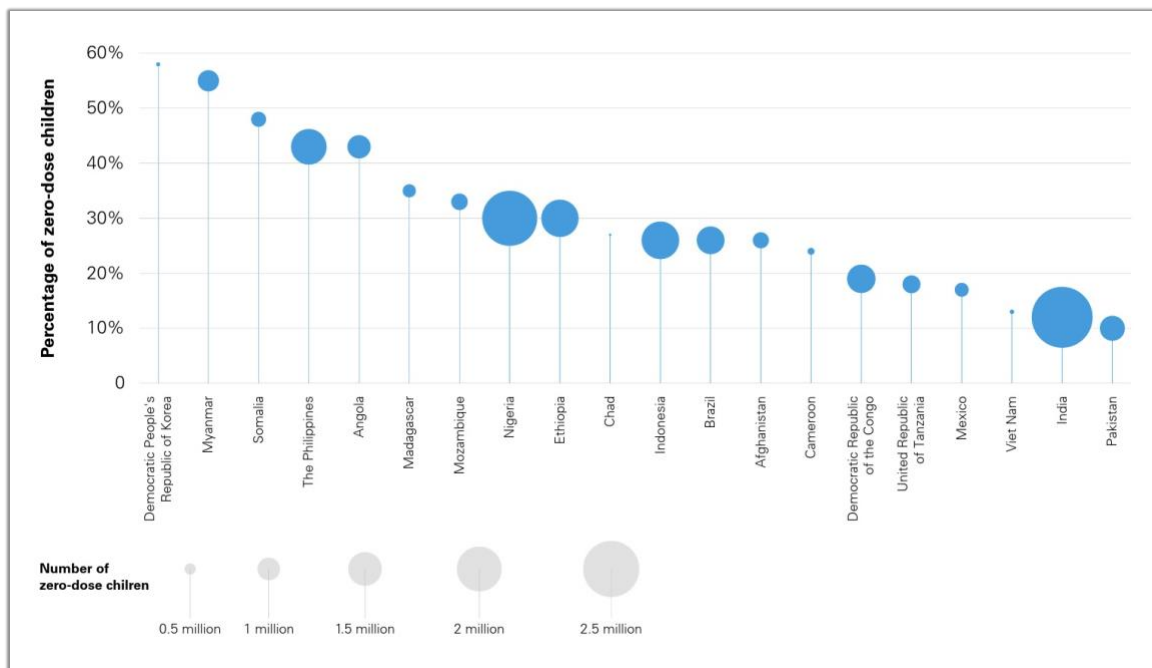


Figure 1. Top 20 countries with the largest numbers of zero-dose children.

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 right 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's a 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 manufacturing.

MAP + Biometrics Innovation

Microneedle Vaccine Patches (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 are thermostable and 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

This integration represents a meaningful step forward in how vaccines can be delivered, tracked, and trusted, particularly in low-resource and last-mile settings.

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 manufacturing.

Alignment with Nigeria's Vaccine Policy, (2021)

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

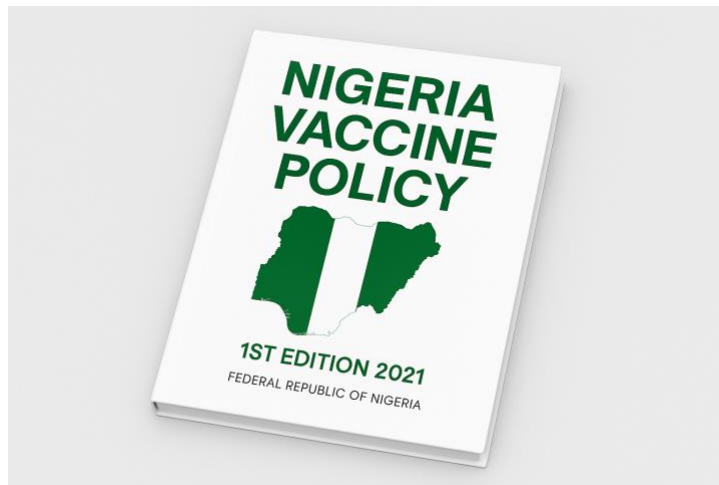


Figure 2. Nigeria's Vaccine Policy (2021), highlighting national goals for innovation, equitable access, and domestic vaccine production.

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.

As Nigeria works toward full ownership of its vaccine supply chain by 2028, feasibility pilots like this will be instrumental in shaping scalable, locally driven delivery models that strengthen future manufacturing and distribution systems.

The planned introduction of active MAPs in Phase III of this pilot represents a critical step in this process, generating real-world 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 pilot (2025–2030), highlighting timelines, geographic scope, sample size, and key objectives for each stage.

Phase	Timeline	States	Sample Size	Key Focus	Outputs
I (Feasibility and Demonstration)	Oct 2025 – Dec 2026	Lagos, Abuja, Adamawa, Anambra (4 total)	1,200 caregivers (300/state)	Usability, acceptability, biometric match rate (ID linkage success)	Feasibility report, human-factors performance analysis
II (Policy Readiness and Expansion)	Jan 2027 – Jun 2028	Capacity scale-up within the 4 states	+800 caregivers (2,000 total)	Cost and logistics evaluation, subgroup analysis, Policy engagement	Cost-effectiveness analysis, logistics insights report, subgroup findings, and state-level policy briefs
III (Scale-Up and Manufacturing Pathway)	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	Live MAP performance data, workforce training reports, policy and national integration evidence, regulatory submissions and roadmap

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. 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.

Funding Priorities

To move from feasibility to full implementation, LunaVax is actively seeking funding partners committed to innovation, equity, and long-term health system strengthening. The pilot includes field operations, biometric integration, data collection, and policy engagement across four diverse Nigerian states.

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

LunaVax is currently finalizing detailed cost estimates in collaboration with implementation and academic partners. Interested partners are invited to co-invest 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 will be essential to unlock the pilot's full potential by enabling large-scale implementation, advancing regulatory approvals, strengthening delivery infrastructure, and embedding MAP-based models into existing health systems. This next phase requires coordinated leadership across government, global health, industry, and technology sectors to translate pilot insights into sustainable infrastructure and long-term impact.

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

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

Data & Evidence

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.

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

Clinical and operational data will measure system readiness, performance, and safety across diverse implementation settings.

- **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.

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.

- **Community Engagement Insights**

Measure levels of awareness, trust, and participation, providing actionable data for communication strategies.

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.

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 like 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.

The data generated through this initiative, including insights from phase I of this pilot with Harvard Medical School's GCSRT program will inform national policy and guide new delivery models while helping establish local formulation capacity as a critical step toward sustainable MAP production.

As we move from planning to 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 will depend on collective action. By aligning expertise, resources, and commitment, we can turn today's pilot into tomorrow's standard and bring the promise of equitable vaccine access closer to every community.

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