

# MAP Implementation Readiness Framework (MIRF)

*Version 1.1*

*A LunaVax Framework for Assessing Readiness for Vaccine Microarray Patch (MAP) Introduction and Scale-Up*

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## PROJECT FOUNDATION

The Vaccine Microarray Patch (MAP) Implementation Readiness Framework (MIRF) was developed to assess readiness for future MAP introduction and scale-up within immunization systems. It draws on three established implementation science frameworks: the Consolidated Framework for Implementation Research (CFIR),<sup>1</sup> which informed its readiness constructs; Proctor's Implementation Outcomes Framework,<sup>2</sup> which informed constructs such as acceptability and feasibility; and the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) Framework,<sup>3</sup> which informed the link between readiness and real-world implementation.

MIRF is intended as an initial discussion and planning framework. It will first be applied in LunaVax's planned Phase III effectiveness-implementation study of a needle-free measles-rubella microarray patch in Nigeria. The study will explore how baseline MIRF scores relate to implementation outcomes observed during the trial. Findings will inform refinements to domain scoring, readiness thresholds and future versions of the framework.

## EXECUTIVE SUMMARY

MAPs have emerged as a promising innovation that could simplify vaccine delivery, reduce cold-chain dependence and expand access in underserved communities.<sup>4</sup> Growing evidence supports their safety, immunogenicity and technical feasibility,<sup>5,6</sup> yet less attention has been given to the factors that influence successful introduction and scale-up within real-world immunization programs.

This discussion brief introduces the LunaVax MIRF, a tool informed by implementation science to support planning, pilot design, research, stakeholder engagement and policy discussions on MAP introduction. Early assessment can help identify opportunities, challenges and evidence gaps before broader implementation begins.

MIRF assesses five readiness domains:

- Acceptability
- Usability
- Operational Feasibility
- Workforce Readiness
- Institutional Readiness

Each domain is scored from 0 to 20 and combined into a 0–100 MIRF Readiness Index to guide planning across diverse immunization settings, with any domain scoring 0–7 flagged as a priority gap.

## WHY READINESS MATTERS

Health innovations with strong clinical evidence have often faced challenges during real-world implementation.<sup>7</sup> In this brief, implementation readiness refers to the extent to which individuals, organizations, systems and implementation environments are prepared to support the adoption and integration of a new intervention. This builds on established readiness concepts in implementation science, including organizational readiness for change<sup>8</sup> and readiness for implementation within CFIR.<sup>1</sup> Readiness is often a critical determinant of whether a promising technology can be integrated, sustained and scaled within immunization programs.

Key readiness considerations include:

- Community acceptance and trust
- Ease of use for frontline health workers
- Workflow and system integration
- Workforce preparedness and training
- Documentation and accountability systems
- Operational and financial sustainability

For MAPs, these factors are likely to be central to successful introduction through routine immunization services, outreach and campaigns. Adoption may require changes to workflows, training, documentation and community engagement. Assessing these considerations early can help identify barriers and inform implementation planning.

## INTENDED USERS

MIRF is intended for organizations involved in MAP introduction and scale-up, from product development to service delivery:

- Government and Public Health Agencies: Assessing preparedness for MAP introduction and scale-up within national and subnational immunization programs.
- Health Facilities and Service Delivery Teams: Understanding the workforce, training and operational requirements of MAP adoption.
- Researchers and Academic Institutions: Designing implementation studies, readiness assessments and human-factors evaluations.
- Global Health Organizations and Implementation Partners: Supporting program planning, community engagement, capacity building and field deployment.
- Vaccine Developers and Manufacturers: Identifying usability and implementation considerations during product development.
- Funders and Investors: Understanding implementation risks and scalability.

By providing a shared structure for assessing readiness, MIRF can help these stakeholders align efforts and set priorities before MAP introduction.

## MR-MAP PRODUCT LANDSCAPE

MAPs consist of hundreds to thousands of microscopic projections coated with, or composed of, a dry vaccine formulation. When applied to the skin, the projections penetrate only the superficial skin layers and release the vaccine, after which the patch is removed. MAPs do not require reconstitution or syringes, may reduce cold-chain requirements and are generally perceived as less painful than injections.<sup>4, 9, 10</sup>

Two measles-rubella MAP (MR-MAP) candidates are among the most advanced vaccine MAPs in clinical development (Table 1).<sup>5, 6, 11</sup>

**Table 1.** Leading MR-MAP Candidates

|                         | Micron Biomedical                                                                                                                            | Vaxxas                                                                              |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>MAP Type</b>         | Dissolving patch with vaccine-containing projections                                                                                         | Solid patch with vaccine-coated projections                                         |
| <b>Application</b>      | Applied manually with thumb pressure; built-in indicator confirms adequate force                                                             | Applied using a single-use spring-loaded applicator                                 |
| <b>Wear Time</b>        | Approximately 5 minutes                                                                                                                      | Approximately 10 seconds                                                            |
| <b>Application Site</b> | Wrist                                                                                                                                        | Deltoid or thigh                                                                    |
| <b>Clinical Status*</b> | Phase 1/2 completed in The Gambia in adults, toddlers and 9-month-old infants                                                                | Phase 1 completed in Australia in adults                                            |
| <b>Key Finding</b>      | Safe and well tolerated; immune responses comparable to subcutaneous injection in vaccine-naïve infants; strong caregiver preference for MAP | Safe and well tolerated, with immune responses comparable to subcutaneous injection |

\* As reported in published literature at the time of writing.<sup>5, 6, 12, 13</sup>

Differences in application method, wear time and application site have direct implications for usability, health worker training and workflow integration. As more MAP products advance, readiness assessments will need to account for product-specific characteristics. MIRF is designed to support this across diverse MAP technologies and implementation contexts.

## MIRF DOMAIN DEFINITIONS

Domain definitions are specific to MIRF. Acceptability and Operational Feasibility are adapted from Proctor's implementation outcomes.<sup>2</sup> Usability follows ISO 9241-11.<sup>14</sup> Workforce Readiness and Institutional Readiness build on organizational readiness theory<sup>8</sup> and CFIR.<sup>1</sup> Usability concerns the patch and its application; Workforce Readiness concerns staff and organizational preparedness.

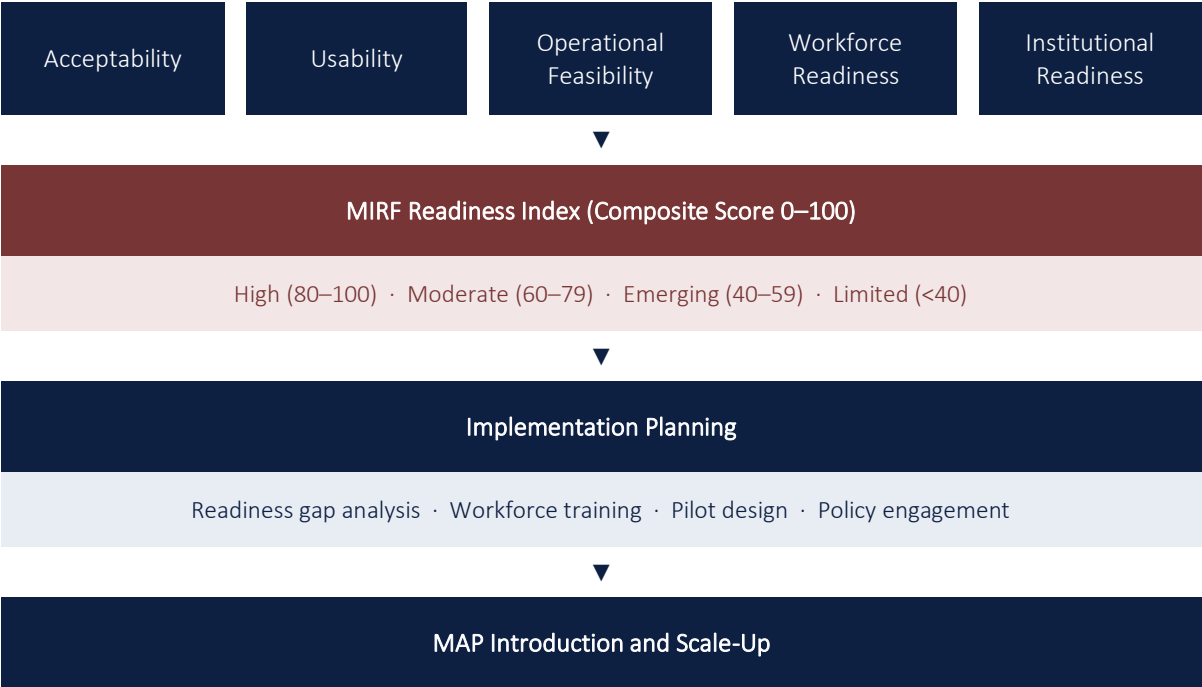
**Table 2.** MIRF Domain Definitions

| Domain                         | Key Respondents                                                  | Definition                                                                                                                                          | Considerations                                                                                                                                         | Example Data Sources                                                                                                               |
|--------------------------------|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| <b>Acceptability</b>           | Caregivers, communities, HCWs and CHWs                           | The degree to which intended users perceive or anticipate MAP vaccination to be agreeable, desirable and satisfactory                               | Trust in MAP technology; preference relative to injections; willingness to recommend MAP vaccination                                                   | Caregiver and community perception surveys, vaccine confidence indicators, health worker interviews                                |
| <b>Usability</b>               | HCWs and CHWs                                                    | The extent to which intended users can correctly perform MAP administration with effectiveness, efficiency and satisfaction in their context of use | Ease of learning; intuitiveness of application; error prevention and correct application; suitability across health worker roles                       | Observed competency checklist and time to correct application during a standardized demonstration patch session; SUS <sup>15</sup> |
| <b>Operational Feasibility</b> | Facility leads, HCWs, CHWs and program managers                  | The extent to which MAP delivery can be successfully carried out within existing immunization systems                                               | Fit with clinic and outreach workflows; resource and cost requirements; logistics and supply-chain readiness; digital infrastructure, where applicable | Facility capability assessment, workflow mapping, storage and supply-chain review                                                  |
| <b>Workforce Readiness</b>     | HCWs, CHWs and program managers                                  | The preparedness of the workforce and implementing organization to adopt, support and sustain MAP implementation                                    | Leadership engagement; staffing capacity; training and supervision structures; implementation climate; perceived workload impact                       | Staffing and workload review, training and supervision records, structured interviews with facility leads                          |
| <b>Institutional Readiness</b> | Ministries of Health, implementing partners and program managers | The degree to which broader systems, stakeholders and institutions are prepared to support MAP deployment                                           | Stakeholder engagement; policy alignment; documentation and information systems; implementation planning and governance                                | Policy and document review, stakeholder interviews, review of reporting and information systems                                    |

HCW: health care worker; CHW: community health worker; SUS: System Usability Scale.

Example data sources are illustrative and may be adapted locally. Baseline indicators are converted to domain scores using the MIRF User Guide (available on request). When predicting implementation outcomes, measure readiness and outcomes with different instruments to avoid circularity.

Figure 1. MIRF Overview



MIRF combines five readiness domains, assessed before implementation, into a composite readiness index to inform planning for MAP introduction and scale-up.

## MIRF READINESS INDEX

The MIRF Readiness Index provides a structured approach for summarizing implementation readiness across the five framework domains. Each domain is scored from 0 to 20, yielding a composite score from 0 to 100. Higher scores indicate greater implementation readiness.

### Scoring Methodology

Domain scores are based on predefined indicators drawn from structured interviews, surveys, observations and record reviews. Multiple sources of evidence may contribute to a single domain score, combined using the respondent selection, indicator definitions, conversion rules and weighting procedures in the MIRF User Guide. Standardized instruments such as the SUS are scored according to their published guidance before conversion to MIRF domain scores.

Categories apply equally to domain and total scores:

**Table 3.** MIRF Readiness Categories

| Domain Score | Total Score | Category | Interpretation                                        |
|--------------|-------------|----------|-------------------------------------------------------|
| 16–20        | 80–100      | High     | Nearly all indicators met; few or no significant gaps |
| 12–15        | 60–79       | Moderate | Most indicators met; some gaps to address             |
| 8–11         | 40–59       | Emerging | Some indicators met; important gaps to address        |
| 0–7          | Below 40    | Limited  | Few indicators met; substantial preparation required  |

Any domain scoring 0–7 is flagged as a priority gap, regardless of the total score. Results should report all five domain scores alongside the total, as a strong total can mask a weak domain. Category ranges will be refined in future versions of MIRF as field evidence accumulates.

## MIRF Readiness Scorecard

Site or setting: \_\_\_\_\_ Date of assessment: \_\_\_\_\_

Assessed by: \_\_\_\_\_

| Domain                  | Score (0–20) | Category | Priority Gap (0–7)       | Notes |
|-------------------------|--------------|----------|--------------------------|-------|
| Acceptability           |              |          | <input type="checkbox"/> |       |
| Usability               |              |          | <input type="checkbox"/> |       |
| Operational Feasibility |              |          | <input type="checkbox"/> |       |
| Workforce Readiness     |              |          | <input type="checkbox"/> |       |
| Institutional Readiness |              |          | <input type="checkbox"/> |       |
| <b>Total MIRF Score</b> | ___ / 100    |          |                          |       |

## MIRF Readiness Summary

|                                                                                                                                    |       |
|------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>Overall Readiness Category (select one)</b>                                                                                     |       |
| <input type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Emerging <input type="checkbox"/> Limited |       |
| Key Strengths:                                                                                                                     | _____ |
| Priority Gaps:                                                                                                                     | _____ |
| Recommended Next Steps:                                                                                                            | _____ |

## MIRF IN PRACTICE: FIRST APPLICATION

The Phase III study, to be conducted by LunaVax Institute Nigeria, will apply MIRF across Lagos, Adamawa and Anambra states and the Federal Capital Territory, with assessment procedures tested in the preparatory pilot before baseline assessment at all sites.

**Site selection.** In this study, sites are selected using safety, regulatory and Good Clinical Practice (GCP) criteria defined in the study protocol, not MIRF scores. MIRF is assessed at baseline at all sites, so it can be evaluated against implementation outcomes without influencing site eligibility.

**Assessing usability before introduction.** Because MIRF is designed for use before MAP introduction, usability is assessed through a standardized demonstration session using a non-antigen training patch that matches the study product's design. This mirrors simulated-use approaches in MR-MAP human-factors research.<sup>11</sup> The study will also explore whether simulated-use scores predict usability and administration fidelity during real-world delivery.

**Assessment and scoring.** To support consistency across sites, MIRF assessments in the study are planned to be conducted by trained assessors independent of site staff, with completed assessments reviewed centrally before scores are finalized.

**Addressing gaps before activation.** Sites with priority gaps may receive targeted support, such as additional training or workflow adjustments, before activation. Baseline scores will be retained for analysis, and any remediation will be documented and considered when evaluating MIRF's predictive performance.

**Beyond the study.** Ministries of health, implementing partners and other stakeholders can apply MIRF across states, districts or facilities to identify strengths, gaps and priority investments before MAP introduction. Low scores indicate where support is needed, not settings to exclude.

## PRIORITY RESEARCH QUESTIONS

Building on recent expert priorities for MR-MAP implementation research,<sup>16</sup> key questions include:

- How do caregivers and communities perceive MAP vaccination compared with injections?
- How do health workers rate MAP usability, and how often do administration errors occur in routine use?
- How does MAP delivery fit within existing clinic, outreach and campaign workflows?
- What training and supervision approaches best prepare different types of health workers, including community health workers?
- How should policies, documentation and information systems be adapted to support MAP introduction?
- Does baseline readiness, as measured by MIRF, predict implementation outcomes across sites and settings?

Together, these questions reflect MIRF's five readiness domains and its validation. Answering them will generate the evidence countries need to move MAPs from promise to practice.

## IMPLEMENTATION CONSIDERATIONS

Before applying MIRF, organizations should consider the following contextual factors:

- Country-specific immunization policies and regulatory requirements
- Workforce structure and training models
- Cultural perceptions of vaccination and local language needs
- Urban, rural and hard-to-reach settings
- Resource availability and health system capacity

Data collection may be adapted to local context, for example by translating tools or adjusting interview formats. Domains and scoring should be applied as specified in the MIRF User Guide, so results remain comparable across settings.

## FUTURE DIRECTIONS

MIRF is an initial contribution to MAP implementation science and a starting point for readiness assessment, research and stakeholder engagement. Future work will focus on validating and refining the framework, including:

- Examining whether baseline scores predict outcomes, and which domains matter most
- Evaluating whether targeted remediation after baseline improves implementation outcomes
- Comparing simulated-use usability with real-world usability and administration fidelity
- Assessing scoring reliability, including agreement between independent assessors
- Refining domain scoring and category ranges based on field evidence
- Exploring how readiness differs across routine, outreach, campaign and community-based delivery
- Considering population factors, such as nutritional status and co-infections, that may affect vaccine response

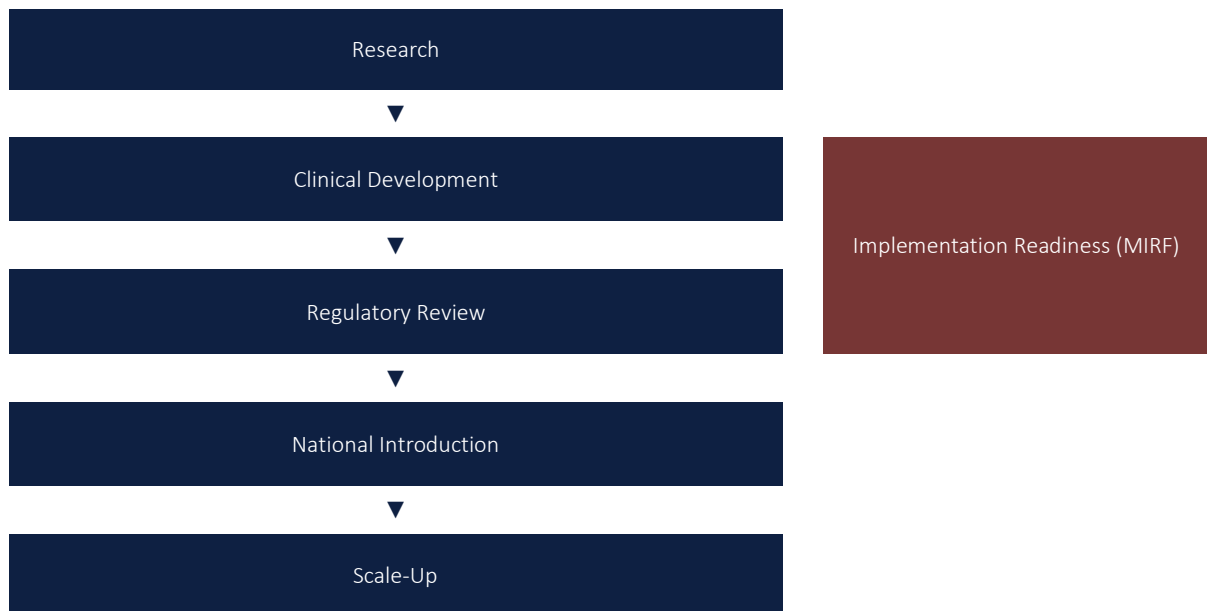
As evidence on MAP self-administration grows, MIRF may be expanded to assess readiness for caregiver-administered delivery, which could reduce reliance on trained health workers in remote and underserved settings. Organizations applying MIRF are encouraged to share their experience with LunaVax to inform future versions.

## ALIGNMENT WITH GLOBAL MR-MAP PRIORITIES

MIRF is designed to address evidence needs raised at the June 2023 meeting of WHO's Product Development for Vaccines Advisory Committee (PDVAC) on MR-MAPs.<sup>11</sup> The meeting identified campaigns (supplementary immunization activities, SIAs) and outbreak response as priority use cases and recommended developing WHO Evidence Considerations for Vaccine Policy (ECVP). Expert input also highlighted the need for implementation studies and research on delivery by community health workers. A subsequent PDVAC update emphasized that clinical, pre-implementation and operational research should inform Phase III design and policy.<sup>17</sup>

A recent CHNRI prioritization exercise identified implementation research priorities for MR-MAPs, including caregiver and vaccinator perceptions, administration errors, workforce and training needs, and supply chain implications.<sup>16</sup> LMIC government respondents emphasized operational and workforce considerations, and the authors highlighted system readiness, which MIRF's five domains are designed to assess. With MR-MAPs anticipated by 2030,<sup>16</sup> countries that assess readiness early will be better positioned for timely introduction and to align evidence with national policy processes, including ECVP.

**Figure 2.** MIRF within the MAP Development Pathway



Readiness assessment can begin alongside clinical development and regulatory review, so countries are ready for introduction once MAPs are approved.

## CONCLUSION

MAPs have the potential to transform vaccine delivery by simplifying administration, reducing cold-chain dependence and expanding access, particularly for children in hard-to-reach communities. Successful introduction, however, will depend not only on product performance but also on the readiness of communities, health workers, delivery systems and institutions.

MIRF provides a structured approach for assessing this readiness across five domains, identifying strengths, gaps and priority investments before MAP introduction. Its first application in LunaVax's planned Phase III study will generate evidence on how readiness relates to implementation outcomes and inform future versions of the framework.

As MR-MAPs move closer to licensure, early investment in readiness will help ensure that MAP introduction is timely, equitable and sustainable.

## Disclaimer

This framework is presented as a discussion and planning tool. It should not be interpreted as an official policy instrument, regulatory standard or implementation guideline. Validation is planned through LunaVax's pilot and Phase III study activities. References to WHO and other organizations do not imply their endorsement of MIRF. The views and conclusions presented are those of the author and do not necessarily reflect the views of Harvard Medical School, the Global Clinical Scholars Research Training Program or any affiliated institution.

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## Version History

Version 1.1 (October 2026) is the first public release, following internal review of Version 1.0 (July 2026).

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