MR MAP candidates in product development

PDVAC MR MAP meeting, June 2023

Courtney Jarrahian
Director, MAP Center of Excellence

PATH

Photo: PATH/Stella Wanjiru/Living Labs/MR MAP project 2022
All photos PATH unless otherwise noted

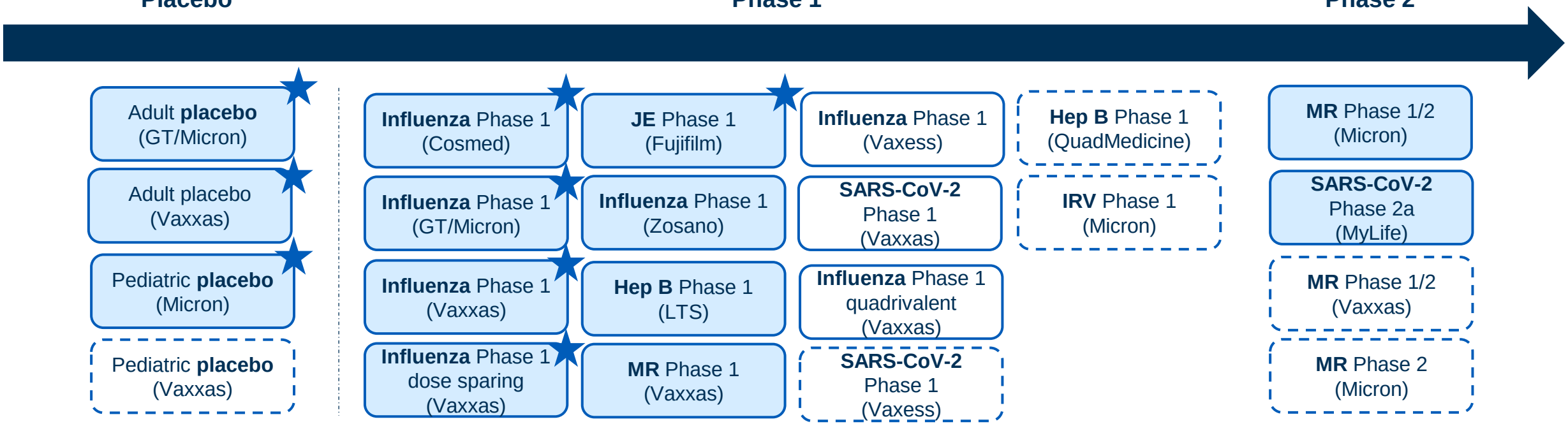
The clinical evidence base for vaccine MAPs is expanding

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

Results are published or anticipated for MR, influenza, SARS-CoV-2, Hep B and JE in Phase 1, as well as Phase 2 results for MR.

Key

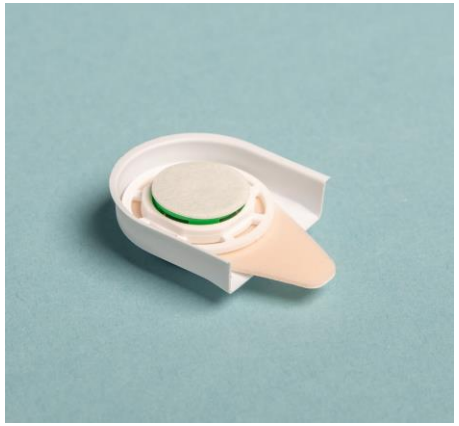
- Published ★
- In progress
- Completed
- Planned



Gavi The Vaccine Alliance · World Health Organization · Bill & Melinda Gates foundation · PATH · unicef

MR MAP candidates

	Micron Biomedical	Vaxxas
Company location	Atlanta, USA Pilot-scale production planned in Germany	Brisbane, Australia Pilot-scale production planned in Australia
MAP type	Dissolving - Fully biodegradable microstructures with antigen concentrated at the tips	Solid coated - Densely packed polymer microstructures coated with vaccine
Application	Applied manually (no applicator required) with integrated force feedback indicator to help with successful application	Integrated single-use, pre-loaded spring applicator provides high velocity application
Wear time	5 minutes	10 seconds
Application site	Wrist	Adults: deltoid Infants: thigh
Clinical status	Phase 1/2 study completed in the Gambia (age de-escalation: adults, toddlers, infants)	Phase 1 study completed in Australia (previously immunized adults aged 18-50)



Micron MAP

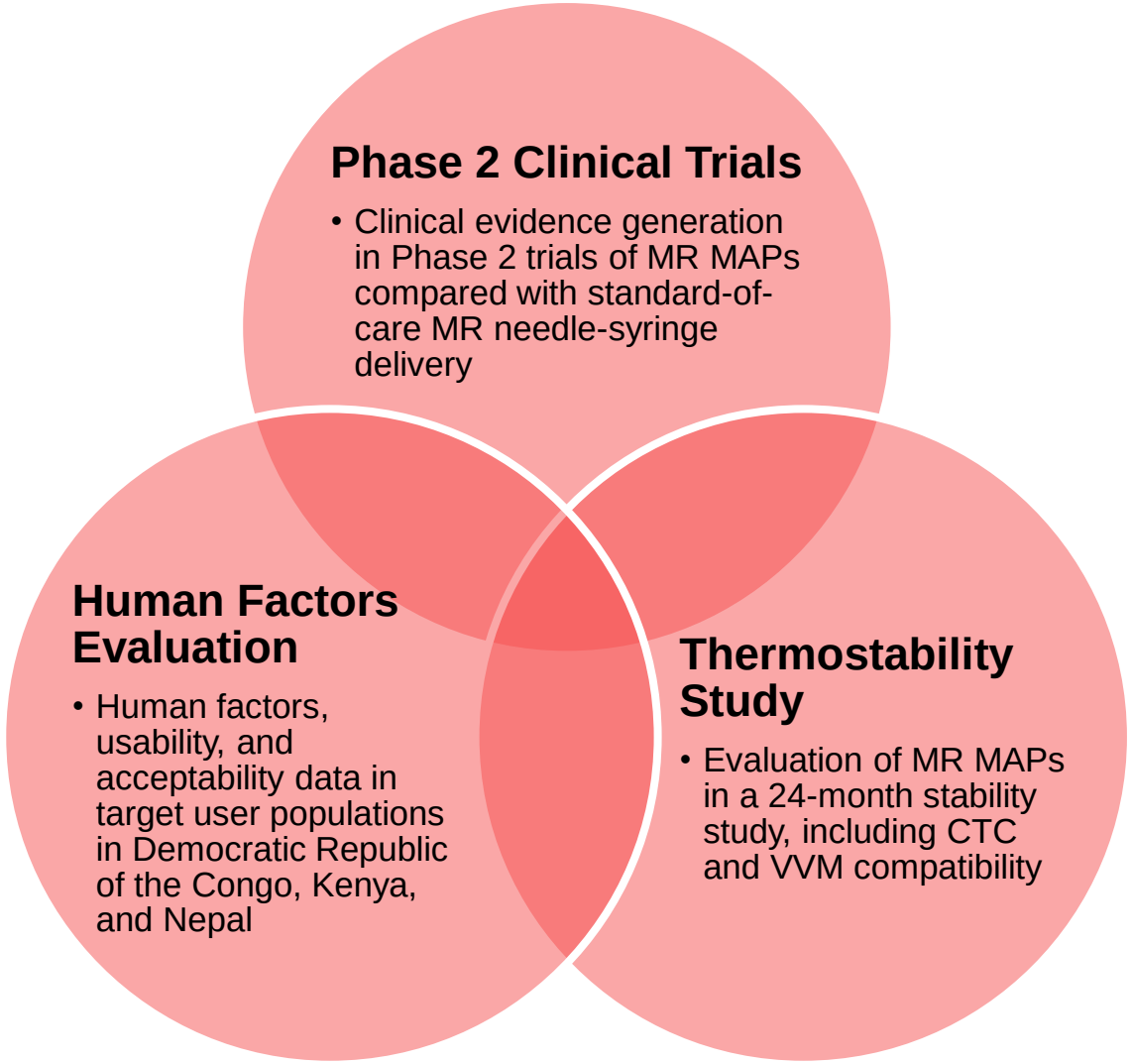
Vaxxas MAP

- Additional MR MAP candidates are in preclinical development (e.g. Inventprise, QuadMedicine)

PATH

PATH's MR MAP workstreams

Objective: Generate data on two MR MAP candidates which (in combination with information on manufacturability and cost) will inform decision to move into a Phase 3 clinical trial.



Phase 2 clinical trials—The Gambia

Two separate randomized, controlled Phase 2 trials are being planned to evaluate both the Micron and Vaxxas MR MAPs.

Primary objectives: Assess safety/tolerability, and immunogenicity of MR MAP compared to licensed subcutaneous vaccine.

Exploratory objective: Explore the acceptability of MAP vaccine delivery (observation of child's response to immunization; caregiver perspectives of MAP delivery and site reactions) as well as characteristics (e.g., wear time; site of administration) of both MAP designs.

Populations:

- Clinical trial: 9-month-old infants, age de-escalation lead-ins incorporated, if needed
- Acceptability: parents/caregivers of infant participants, and parents/caregivers of non-participants.

Status: Study designs under development—opportunity to potentially assess key questions such as different wear times or application sites.

MR MAP human factors evaluation overview

Objective: PATH will conduct an expanded formative human factors study to (1) **identify use-related errors and difficulties** and (2) **understand the acceptability and programmatic fit** of two prototype MR MAP designs.

The formative study has three components.

1. **Pre-test (completed):** designed to refine instructions for use and training; includes simulated use with target user groups (Kenya).
2. **Main evaluation:** includes simulated use and interviews with target user groups as well as stakeholders at a variety of levels (Democratic Republic of the Congo, Nepal, Kenya).
3. **Clinical trial** (exploratory objective): acceptability data will also be collected as part of the Phase 2 clinical trials, including data on infant acceptability and parent/caregiver acceptability (The Gambia).

Areas of Inquiry	
Human factors / usability	Including observed use difficulties, use errors, and close calls; user interface design flaws; and potential for reuse.
Acceptability	Perceived advantages and disadvantages of each MAP device; recommendations to improve the device, labeling, and/or training materials; comfort and appropriateness of caregiver or community health worker administration.
Programmatic fit	MAP fit at patient- and immunization-system levels; best practices and challenges for introducing a new technology in target settings.

PATH

Kenya human factors pre-test (2022)

Objectives

1) To assess usability of the MAP and IFU for both MR MAP candidates

2) To identify potential use difficulties and errors related to the IFU and training procedures

3) To iteratively refine both IFU and training procedures.

Participants: 32 facility-based HCPs and CHWs in urban and rural settings

Training: Very minimal (verbal step-by-step explanation of IFU and display of sample) or no training (IFU only)

Data collection: Observation of simulated use on a manikin followed by interview

PATH/Stella Wanjiru/Living Labs/MR MAP project 2022

User testing MAP prototypes in Kenya.

Definitions: HCP – health care provider; CHW – community health worker; IFU – instructions for use.

Human factors pre-test findings

Topic	Insight for both MAPs
Successful MAP delivery	Only a few participants completed all distinct actions needed for correct MAP use.
Usability observations	Some participants made use errors that could be attributed primarily to the minimal or no training provided for a new device.
Expressed ease of use	Participants found more than half of distinct actions easy to do.
Expressed confidence in using MAP	Most participants expressed confidence in using the MAPs.
Expressed confidence in using IFU (only asked in Round 2)	Without any training, only about half of participants expressed feeling confident about applying the MAP following the IFU.

Key learnings

Training: Participants would benefit from training and practice that allows them to see how to administer the device and experience the feel and sound of correct administration indicators (the "click").

Programmatic feasibility: Based on their use experience, participants also made the following recommendations for each device.

- *Micron:* it would be beneficial to reduce the wear time (one-minute was used in the pre-test).
- *Vaxxas:* change the site of administration to the arm (same as the subcutaneous MR vaccine).

PATH

Main human factors evaluation (2023)

Location

PATH is conducting the evaluation in three countries—Kenya, DRC, and Nepal.

Objectives

1. Determine if the key steps for use can be completed with no device-related use errors.
2. Understand acceptability, confidence in use, and suitability of the devices for users.
3. Obtain initial feedback on potential suitability of packaging, administration, and disposal of materials in the intended scenarios of use.
4. Assess the auto-disable features of the MAP devices to prevent reuse.

Photo: PATH/Aaron Joel Santos

Main human factors evaluation

Study design

- **Simulated use and interviews:** after training, participants will be asked to deliver a simulated vaccination using a manikin; an observation guide will be used to capture use experience.
- **Stakeholder interviews:** qualitative interviews will be conducted with key stakeholders.

Participants (per country)

- **Simulated use:** up to 32 healthcare providers and community health workers in urban and rural settings, including facility-based and outreach workers.
- **Stakeholders**: up to 12 stakeholders such as Ministry of Health Staff including health officials at the regional and district levels; community organizations; and representatives of the private health sector.

Photos: PATH/Stella Wanjiru/Living Labs/MR MAP project 2022.

Training: in alignment with the target product profile, minimal training will be provided on both devices and will include the following:

- A **short presentation** with a brief introduction of the MAP technology.
- A **live demonstration** of MAP administration on a manikin. The IFU will be used during the demonstration.
- A **guided hands-on practice** applying a single MAP to the manikin with an opportunity to ask questions and receive feedback from study staff.

Timeline: data collection is planned for 2023 (starting with Kenya in July) with analysis and reporting to be completed in the first half of 2024.

PATH


PATH