# Microarray patches: Opportunities for global health impact and health equity

## Technology overview and development resources

Workshop for Developing Countries Vaccine Manufacturers Network International

December 11, 2023

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PATH

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

# Outline

- Background
- Microarray patch (MAP) technology overview
- MAP target product profiles (TPPs)
- Addressing MAP challenges
- Vaccine Innovation Prioritisation Strategy (VIPS)

# Question for the audience

What do you see as the biggest barrier(s) currently limiting access to routine immunizations?

A. Inadequate infrastructure for cold chain leading to vaccine wastage due to temperature exposure.

B. Inadequate delivery service points (e.g., remote populations).

C. Inadequate availability of appropriately trained health care workers.

D. Missed opportunities due to reluctance to open multidose vials.

E. Vaccine hesitancy or fear of injections and needles.

F. Other (put in the chat).

Background

MAP technology overview

MAP Target Product Profiles

Addressing MAP challenges

Vaccine Innovation Prioritisation Strategy


PATH is a global team of innovators working to eliminate health inequities so people, communities, and economies can thrive.



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PATH'S MISSION

# Advance health equity through innovation and partnerships.

Photo: PATH/Christopher Nelson

# One PATH, one mission, many experts

More than 1,500 strong, our global team includes experts and thought leaders from dozens of specialties including:

- **Product development**—contraceptives, rapid diagnostics, and other devices.
- **Primary health care**—people-centered health systems strengthening.
- **Vaccines and essential medicines**—development, formulation, manufacturing, and rollout.
- **Digital transformation**—electronic immunization registries and other real-time systems.
- **Epidemic preparedness and response**——disease surveillance, responder training, and coordination.
- **Advocacy and communications**—elevating community priorities, influencing local and global stakeholders.

# PATH Medical Devices and Health Technologies program

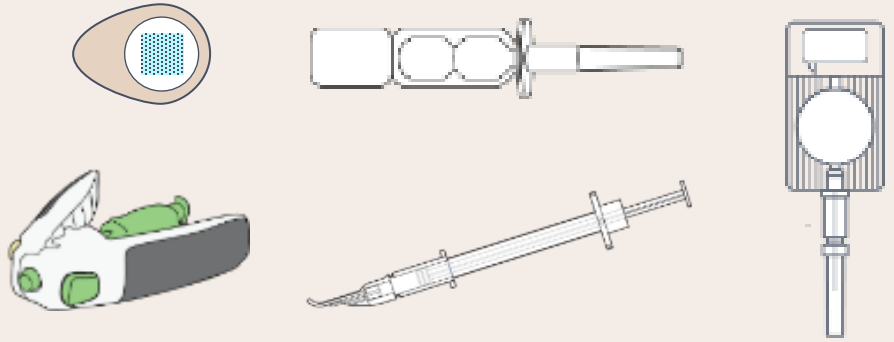
**We offer end-to-end product development services**, from technology ideation to impact.

We are **a multidisciplinary group** of public health researchers, clinicians, scientists, engineers, designers, health economists, project managers, and business strategists in the following portfolios:

- Formulation Technologies
- Health Technologies for Women and Children
- Living Labs Initiative
- Supply Systems & Equipment
- **Packaging & Delivery Technologies**

Device staff also work closely with and support the PATH Center for Vaccine Innovation and Access.

The **Packaging & Delivery Technologies Portfolio** works to identify, assess, and advance innovative primary packaging and delivery devices for vaccines and pharmaceuticals that maximize efficacy, increase access, and reduce cost.



*Various packaging and delivery technologies.*

Innovative delivery strategies are needed to eliminate health inequities.



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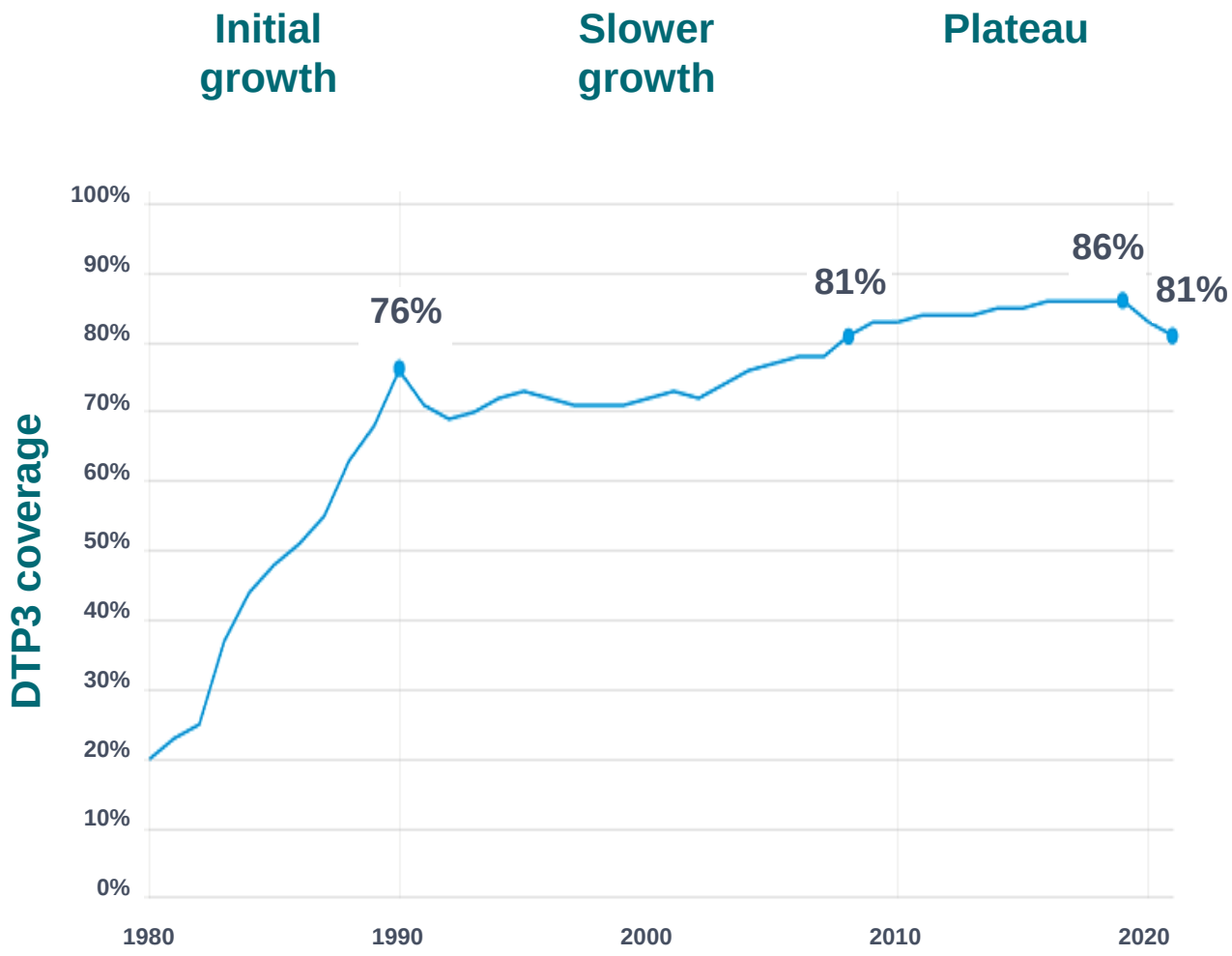
# Global health need: Vaccines that can travel to the people who need them

Progress on global vaccine coverage significantly stalled during the pandemic.

In 2021, there were 18.2 million zero-dose children, primarily in the most disadvantaged communities.

New tools, such as microarray patches, can fill the gap **if they have the right attributes**.

To achieve impact, microarray patches must be paired with innovative delivery strategies.




**Source**: World Health Organization (WHO)/United Nations Children's Fund (UNICEF). *Immunization Coverage Estimates*–2021 Revision. WHO/UNICEF; 2021.

Abbreviation**:** DTP3, diphtheria tetanus toxoid and pertussis.

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# Question for the audience

How familiar are you with the microarray patch platform?

A. Not at all familiar

B. Slightly familiar

C. Somewhat familiar

D. Moderately familiar

E. Extremely familiar

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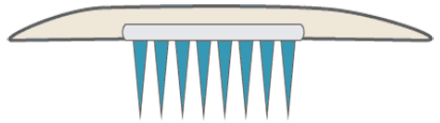
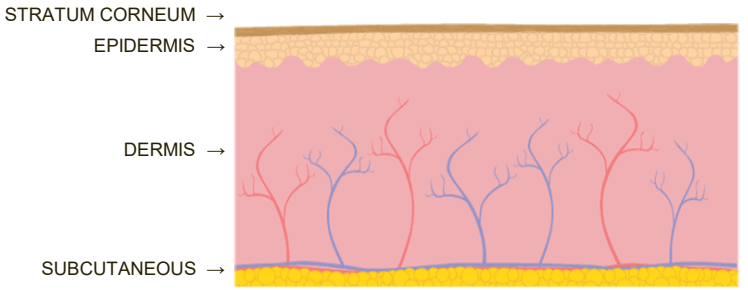
# Microarray patch (MAP) technology overview

- A patch may have **hundreds or thousands of tiny projections**.
- The projections can be **coated with or composed of a vaccine** (dry formulation).
- **The patch is applied to the skin and pressed down** so that the projections penetrate the top of the skin. The vaccine dissolves in the skin, and the patch can be removed.
- The projections only **penetrate the top layers of the skin** to deliver the vaccine.
- It is typically perceived as **less painful than an injection**.
- Some platforms require an **applicator** for delivery (integrated or separate).
- Vaccine microarray patches (MAPs) are in **early-stage development**; it may be a decade or more before a vaccine MAP product could be introduced.

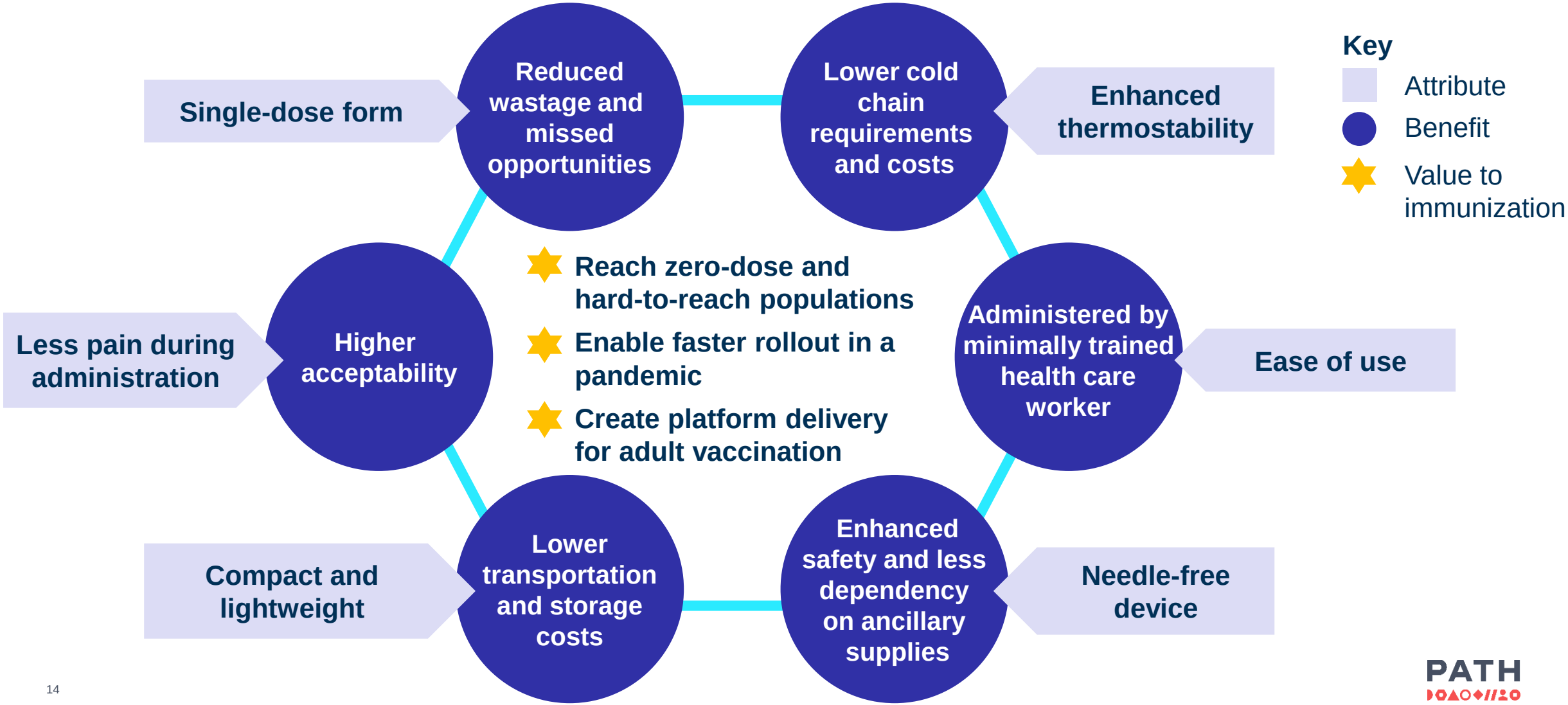





Micron MAP

Vaxxas MAP

# Vaccine MAPs could transform immunization delivery



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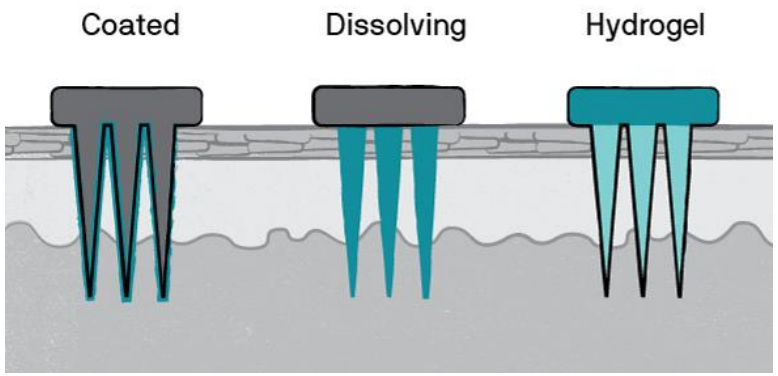
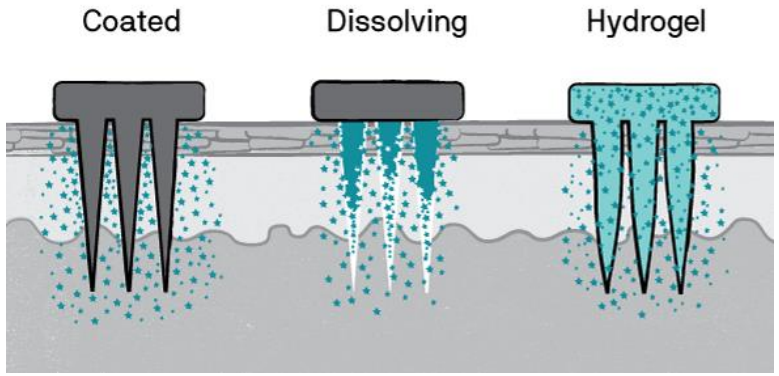
# Types of microneedles

**Step one:** Microprojections are applied.

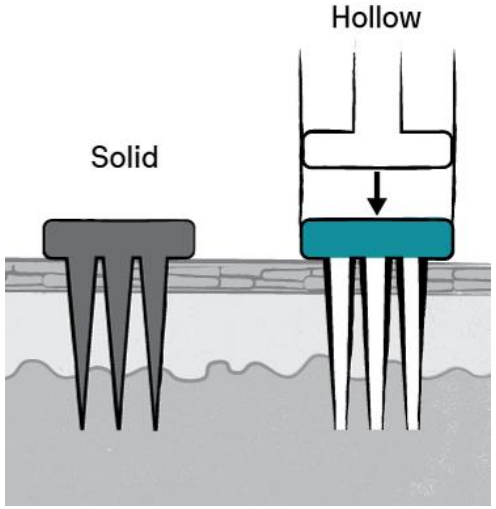
**Step two:** Pharmaceutical is released.

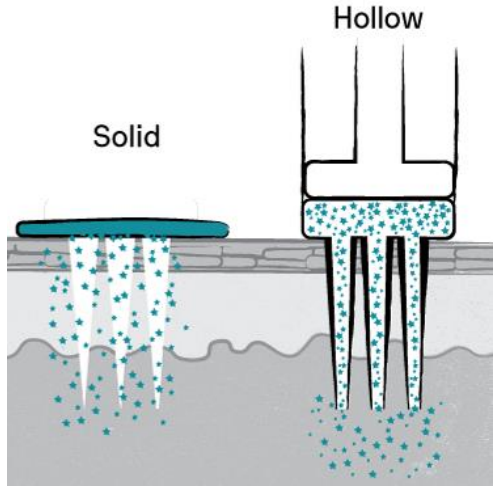
## Microarray patches (MAPs)



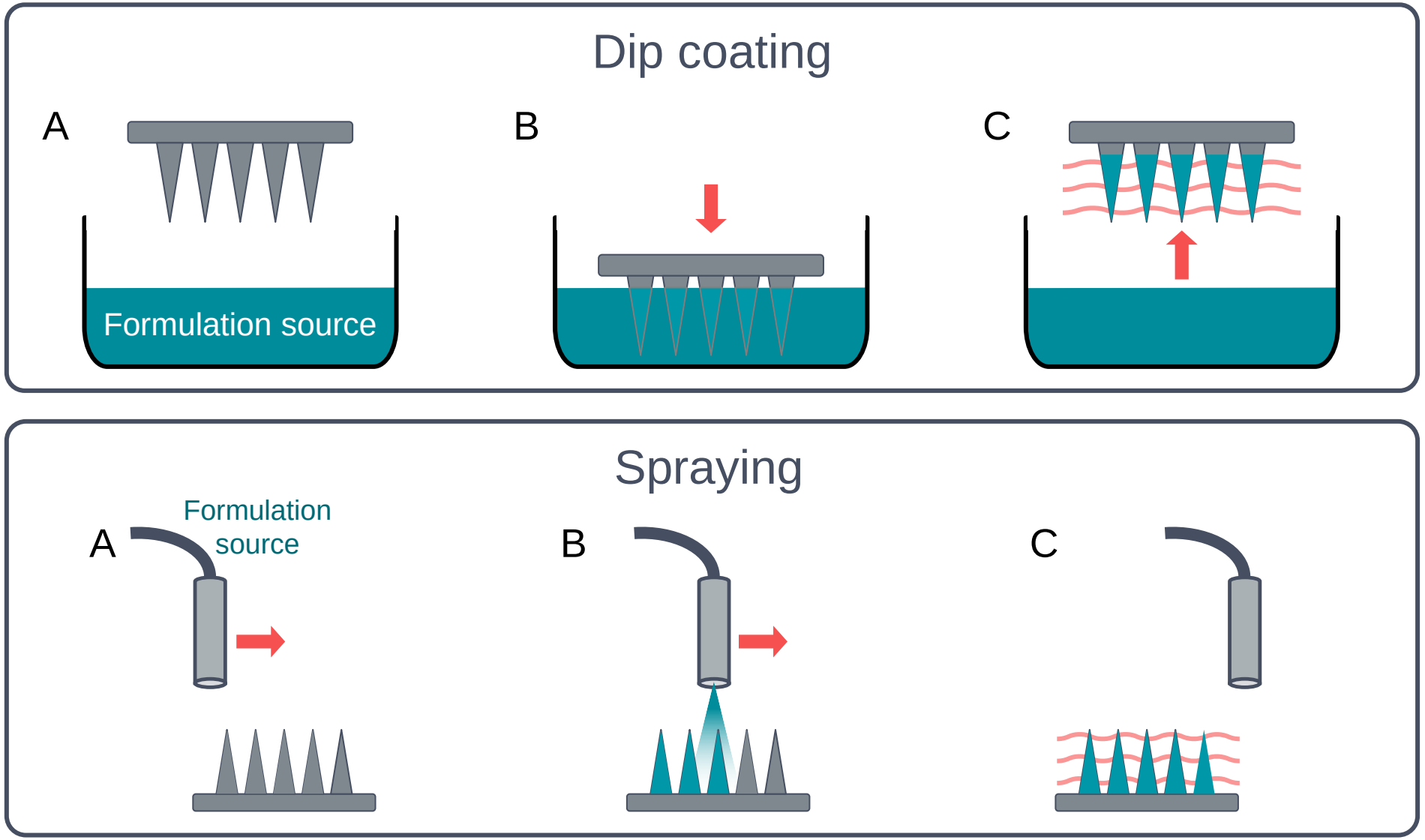




## Liquid delivery via microneedles



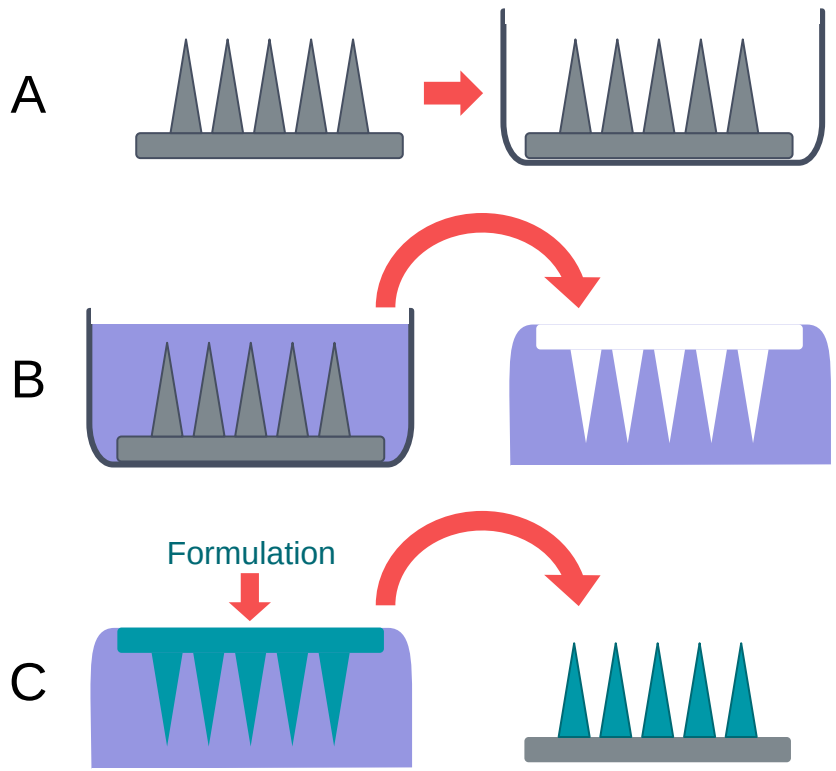



# Manufacturing methods for coated MAPs

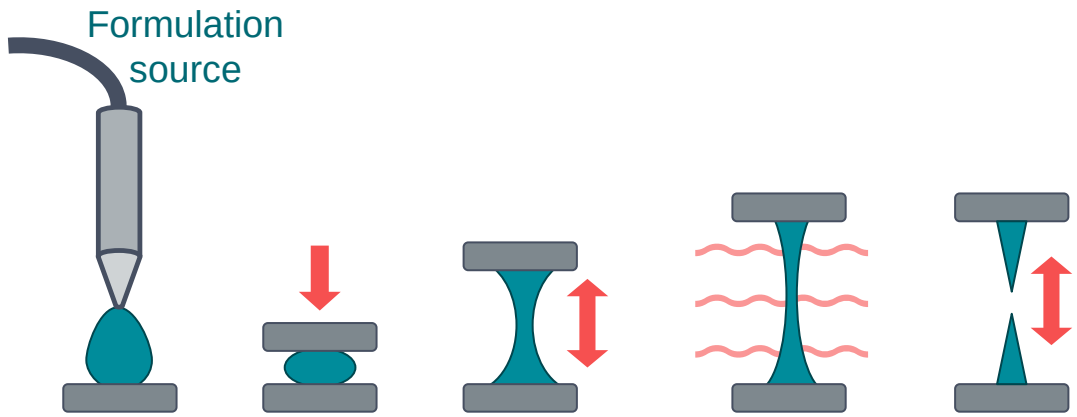


# Manufacturing methods for dissolving or hydrogel MAPs

## Micromolding: Solvent casting




## Surface drawing: Droplet-born air blowing



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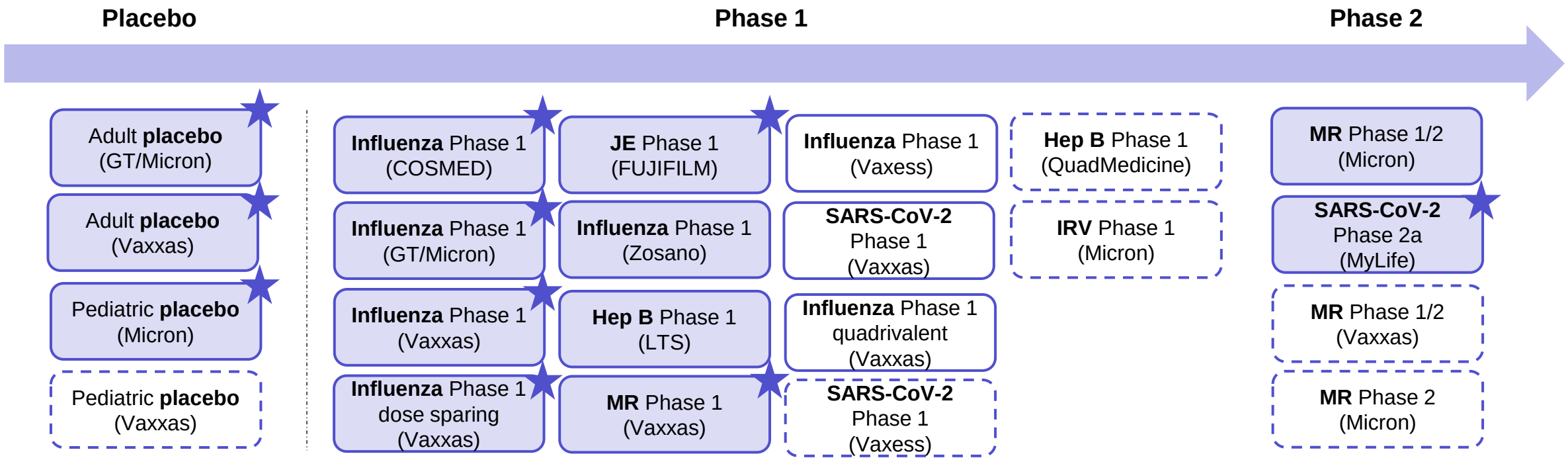
# The clinical evidence base for vaccine MAPs is expanding

Results are published or anticipated for the measles-rubella (MR) vaccine, inactivated rotavirus vaccine (IRV), and the vaccines for influenza, COVID-19 virus (SARS-CoV-2), hepatitis B (Hep B), and Japanese encephalitis (JE) in Phase 1, as well as Phase 2 for MR and SARS-CoV-2.




Abbreviations: GT, Georgia Institute of Technology; LTS, Lohmann Therapie-Systeme.

# First clinical proof of concept of vaccine MAPs in infants

Photo: Micron Biomedical.

Micron Biomedical announces positive measles and rubella vaccination results from first clinical trial of microarray injection-free vaccine delivery in children.

- **First completed Phase 1 & 2 clinical trial in unprimed 9-month-olds** with a **microarray patch (MAP) for measles-rubella (MR) vaccine** in The Gambia, a country where measles is endemic.
- **High and similar seroprotection and seroconversion rates for MR** in all cohorts for both the MAP and subcutaneous (SC) injection.
- **Vaccination by MAP was safe and well tolerated,** with no allergic reactions or related serious adverse events.
- **Over 90% of the parents of toddlers and infants** enrolled in the trial, who **took part in an acceptability survey**, said the **MAP technology would be better than SC injection.**



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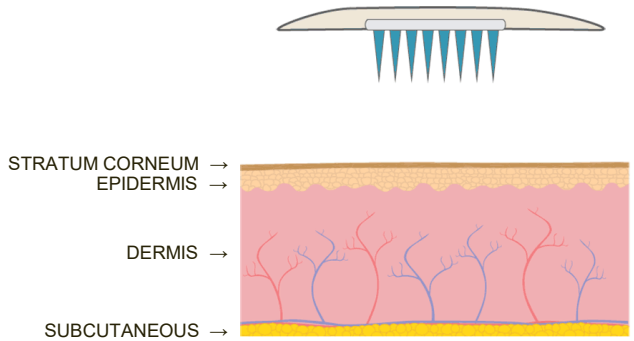
# Why PATH formed the MAP Center of Excellence

## Global health need

Improve presentations of vaccines and pharmaceuticals in low- and middle-income countries (LMICs).

- ⬆ **Ease of use**
- ⬆ **Coverage and equity**
- ⬆ **Thermostability**
- ⬇ **Sharps waste**




## Opportunities

- Increase coverage by enabling alternative delivery scenarios (e.g., delivery by minimally trained personnel).
- Expand access in harder-to-reach populations.
- Deliver vaccines beyond the cold chain.
- Improve adherence to drug regimens.
- Reduce the burden on health systems.

## Challenges

- Product-specific focus, which limits the opportunity for platform-wide efficiencies.
- Siloed information.
- Unclear pathway to manufacturing scale-up and regulatory approval.
- Uncertain market potential in LMICs and return on investment for vaccine/pharmaceutical manufacturers.



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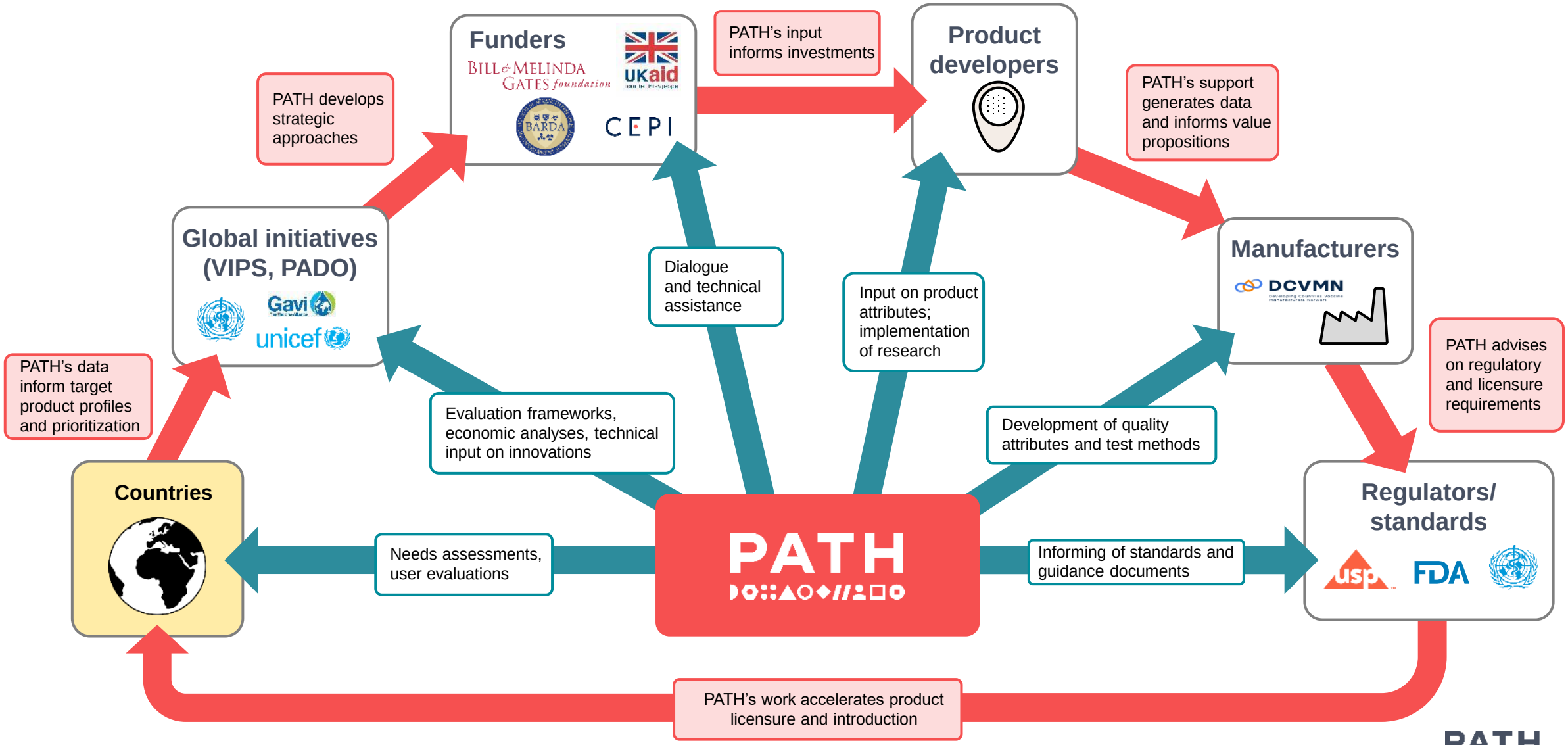
# PATH's role and impact: Microarray patch field






Abbreviations: BARDA, Biomedical Advanced Research and Development Authority; CEPI, Coalition for Epidemic Preparedness Innovations; DCVMN, Developing Countries Vaccine Manufacturers Network; FDA, US Food and Drug Administration; Gavi, Gavi, the Vaccine Alliance; PADO, Paediatric Antiretroviral Drug Optimization; USP, United States Pharmacopeia; UNICEF; United Nations Children's Fund; VIPS, Vaccine Innovation Prioritisation Strategy.

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# PATH's approach to developing target product profiles

**Goals**

- Develop and disseminate target product profiles (TPPs) describing minimally acceptable and optimal attributes of microarray patch (MAP) products with a focus on low- and middle-income country (LMIC) contexts and use cases.
- Guide and inform development efforts of MAP products for high-priority global health applications.

**Key product attributes**

Intended use case, target population, safety, efficacy, dosage, dosing regimen, stability, and disposal.

**Status**

TPPs developed for vaccines against human papillomavirus (HPV), rabies, and COVID-19 are available on PATH's resource page. TPPs developed for measles-rubella (MR) vaccine MAPs are available on WHO's website.

**Unique TPP characteristics**

- TPPs are intended to be broad for a specific indication and are not manufacturer specific.
- Highlight the needs of users and immunization program priorities in LMICs.
- Describe product attributes that will facilitate reaching previously unvaccinated populations and improving health equity.
- Serve as a tool to signal which MAP applications are considered high priorities for global health.



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# Target product profile development process

Review literature

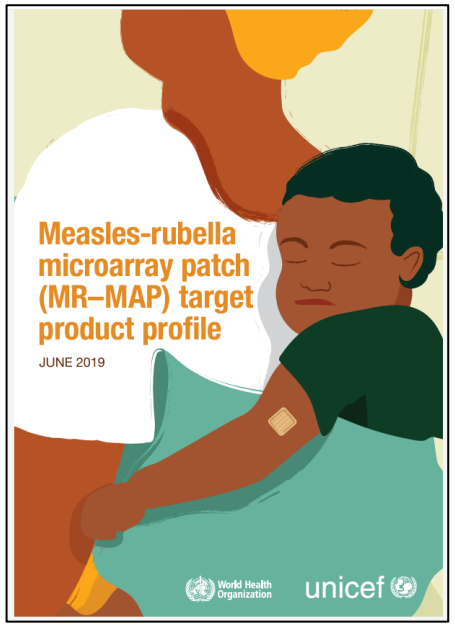
Conduct interviews with global and in-country stakeholders

Solicit feedback from MAP developers and vaccine manufacturers

Post online

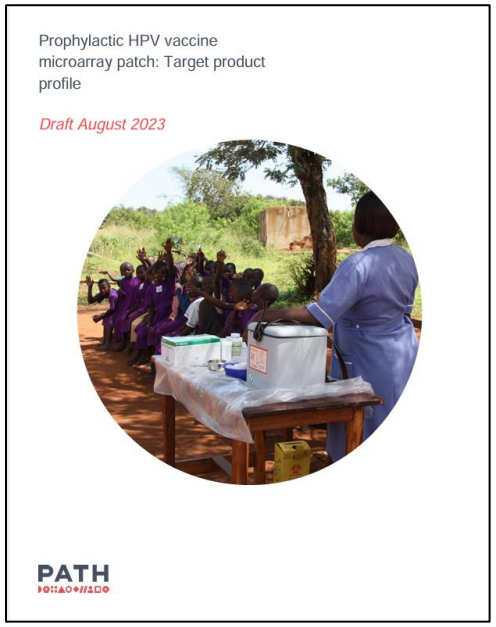
Revise as comments are received and/or new data are generated

## MR vaccine MAP




## Rabies vaccine MAP


## HPV vaccine MAP




## COVID-19 vaccine MAP

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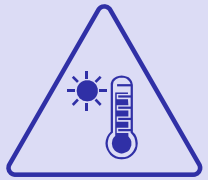
# Key attributes of a vaccine MAP: Usability considerations

| Attribute | Insights |
| --- | --- |
|  Wear time | • Ideally, wear time should be under one minute.<br>• Wear time of several minutes may be acceptable in certain use cases but could create additional burden on the healthcare worker or reduce compliance. |
|  Indicator or applicator | • An indicator or applicator alerts the user that the MAP has been appropriately administered and can only be activated once per MAP.<br>• The device can be used by a lesser trained person (e.g., a community health worker) with minimal training.<br>• The device should be integrated with the MAP and not require the user to put it together. |

# Key attributes of a vaccine MAP: Thermostability considerations

| Attribute | Insights |
| --- | --- |
|  Cold chain volume | • The cold chain volume, including all packaging, should be minimized as much as possible.<br>• Current MAP prototypes are roughly three to five times larger than multidose vial presentations, ranging from 12 to 25 $cm^3$. |
|  Heat stability | • Controlled temperature chain (CTC) allowing a single excursion of the MAP at the end of its shelf life is beneficial for outreach or delivery outside of a health facility but may not be possible for all vaccines.<br>• MAPs could allow for higher temperature vaccine vial monitors (VVMs) than vaccine vials. MAP packaging should include appropriate VVMs. |



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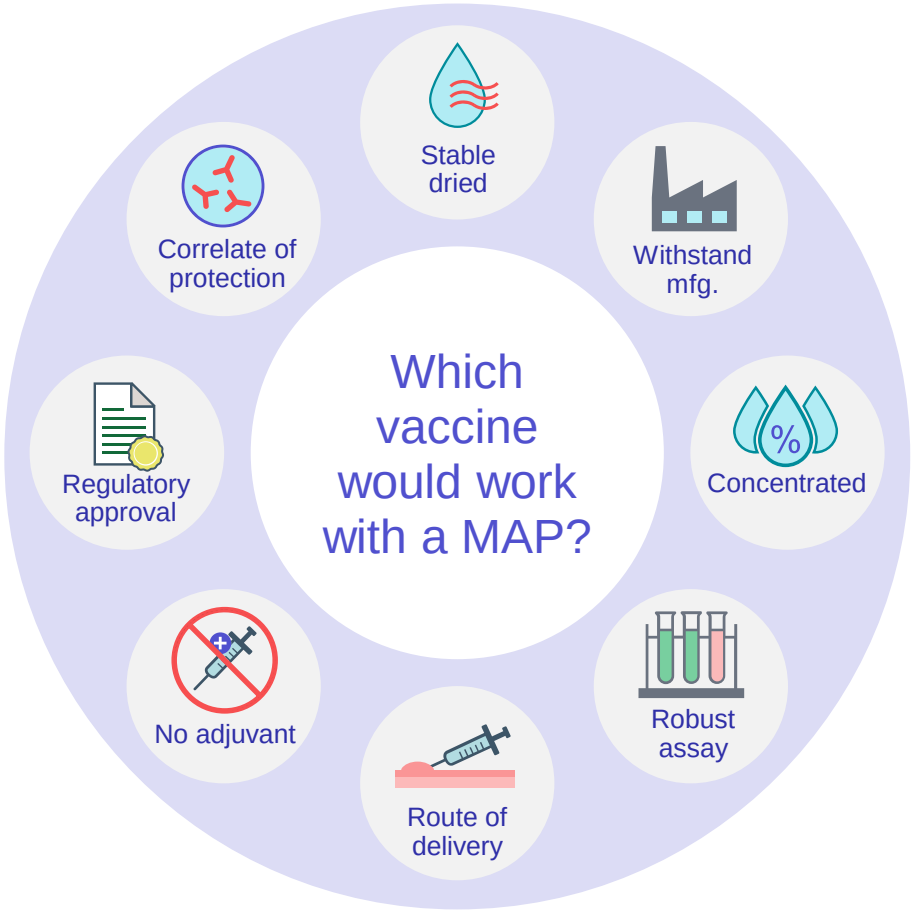
# Key attributes of a vaccine MAP: Manufacturing considerations

| Attribute | Insights |
| --- | --- |
| Manufacturability | • Prior to MAP manufacturing, bulk antigen will require reformulation and possibly concentration.<br>• Dose limitations are based on the type of MAP and manufacturing process. |
| COGS/Price | • Incremental increases in the cost of goods sold (COGS) and price may be acceptable.<br>• Many low- and middle-income countries (LMICs) are price sensitive and may not be willing to pay large price premiums for MAPs despite recognizing their programmatic benefits.<br>• MAPs have the potential to be cost-effective even at higher procurement prices. |

# Vaccine antigen qualities for microarray patches




| | |
|---|---|
| Is the antigen **stable when dried**? | Antigens that can be dried or lyophilized with minimal excipients are best suited to the MAP manufacturing process. |
| Is the antigen **robust** to withstand manufacturing? | During the manufacturing process, the antigen may be exposed to elevated pressures, velocities, or temperatures. Labile antigens may still be used in MAPs but may require longer processing times or require more complex manufacturing. |
| Is the antigen able to be **concentrated**? | The bulk antigen should be concentrated such that a full dose is present in approximately 10 µl or less. |
| Is there a **robust assay** for the antigen? | A robust potency assay is needed during formulation screening and process development. |
| What is the **route of delivery** of the antigen? | Data demonstrating intradermal vaccination is immunogenic increase the chance of success for a MAP. Oral vaccines may not be suitable for MAP delivery. |
| Does the antigen require an **adjuvant**? | Adjuvants may increase the local reactogenicity following MAP vaccination, and adjuvants commonly used in liquid vaccines can be difficult to formulate in a MAP. Novel adjuvants may be necessary if an adjuvant is indicated. |
| Is the antigen approved by a **regulatory** authority? | Both a novel antigen and novel delivery method may increase complexity to achieve regulatory approval. |
| Does the antigen have a **correlate of protection**? | Correlates of protection or other immunological end points may accelerate clinical development. |



Abbreviations: MAP, microarray patch; mfg. manufacturing.

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# Impact of five years of the MAP Center of Excellence: Addressing key challenges for MAPs

**Project goal:** Advance MAPs as a technology platform for high-priority needs in low- and middle-income countries (LMICs).




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# Engagement and dissemination

## Activities

- Published MAP resources website and newsletter.
- Advanced global initiatives with partner organizations (WHO, Gavi, UNICEF, BARDA, CEPI, Bill & Melinda Gates Foundation, etc.):
  - Vaccine Innovation Prioritisation Strategy (VIPS)
  - MR MAP Product Development Working Group
  - BARDA MAP vaccine alliance
  - Global Accelerator for Paediatric formulations (GAP-f)
  - Paediatric Antiretroviral Drug Optimization (PADO)
- Organized and cohosted the Microneedles Conference in May 2023.


PATH/Patrick McKern

Attendees at the 7th International Conference on Microneedles looking at poster presentations.

**Learnings:** Working together, MAPs are being accelerated faster than individual or siloed efforts would allow.

Abbreviations: BARDA, Biomedical Advanced Research and Development Authority; CEPI, Coalition for Epidemic Preparedness Innovations; Gavi, Gavi, the Vaccine Alliance; MR, measles-rubella; UNICEF, United Nations Children's Fund; WHO, World Health Organization.



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# User needs

## Activities

- Global and country stakeholder needs assessments:
  - HPV vaccine
  - Rabies vaccine
  - Typhoid conjugate vaccine
  - Pediatric HIV treatment
  - Pandemic/outbreak response
- Human factors evaluations:
  - HIV prevention
  - Multipurpose prevention (HIV and contraception)
  - Measles-rubella (MR) vaccine

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

User testing MAP prototypes in Kenya.

**Learnings**: In-country studies have identified user needs for training, instructions, and intuitive design of MAP products—demonstration and practice are key.

**Gaps identified**: Implementation research is a critical next step to plan how the unique characteristics of MAPs will fit into programmatic delivery.

# Technical development

## Activities

- Created expert and country-informed target product profiles (TPPs) for microarray patch (MAP) delivery of measles-rubella (MR), human papillomavirus (HPV), rabies, and COVID-19 vaccines, as well as HIV drugs.
- Developed a packaging report with technical, usability, and design considerations.
- Developed and tested a large-area MAP feedback indicator.
- Conducted a thermostability study of MR MAPs.
- Planned and developed protocol for MR MAP Phase 2 clinical trials.


Photo, left: PATH/Patrick McKern and Clara Orndorff

Different methods for force testing MAP feedback indicator prototypes.

**Key questions:** To what extent should product design be optimized before entering the clinic? What trade-offs should be made?

# Manufacturing

## Activities

- Cohosted a three-day manufacturing workshop with Harro Höfliger (Germany) with 75 participants across the industry.
- Conducted an industry survey and interviews to understand the state of the industry and challenges by both developer and MAP type.
- Evaluated manufacturing scale-up processes, costs, and timelines.
- Published a manuscript calling for pilot manufacturing capabilities to be funded in parallel to proof-of-concept clinical trials.

Photo: Harro Hofliger

Attendees at MAP manufacturing workshop discussing automation strategies.

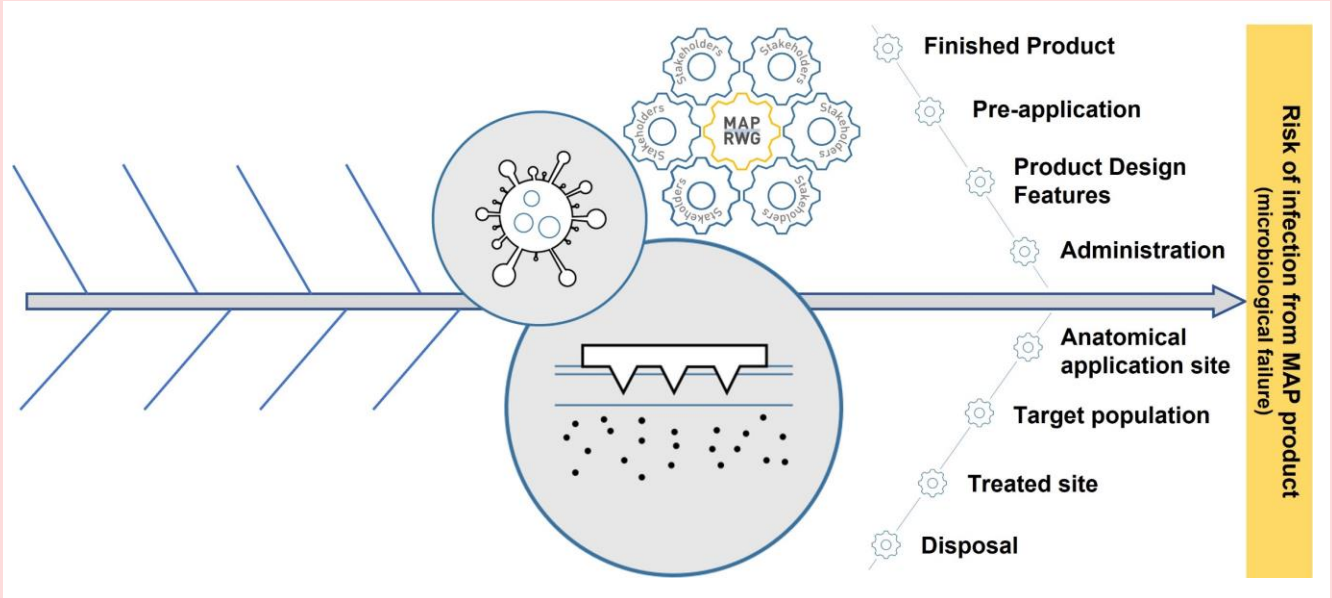
**Learnings:** Design of pilot plants for automated vaccine MAP production.

**Gaps identified:** Manufacturing scale-up through production for Phase 3 clinical research is a critical next step to future licensure.

# Regulatory

## Activities

- Formed MAP Regulatory Working Group:
  - Twenty-three organizations have contributed to date.
  - Six working group meetings were held.
- Created website: www.microneedleregulatory.org.
- Defined dosage form and potential critical quality attributes.
- Published sterility risk assessment.
- Evaluated and developed test method.




Cardiff University

Members of the Sterility Working Group and Regulatory Working Group developed an Ishikawa diagram to summarize key considerations when assessing risk of infection with a MAP product.

**Goal:** To inform publication of a regulatory document to guide MAP development and review (e.g., United States Pharmacopeia chapter on microneedles).

# Business strategy

## Activities

- Measles-rubella (MR) and contraceptive MAP business cases.
- Cost of goods analyses.
- Estimating the dose demand for MR MAPs.
- Cost of delivery for MR MAPs based on PATH's Vaccine Technology Impact Assessment (VTIA) model.
- Cost-effectiveness analyses (hepatitis B vaccine, typhoid conjugate vaccine, HIV prevention, contraception).
- Investment strategies.

## Factors influencing a sustainable market for MAPs

### Affordability
Pricing enables country uptake and allows sufficient return on investment for manufacturers.

### Availability
Robust supply chain and adequate production capacity.

### Assured quality
National regulatory authority and WHO prequalification.

### Appropriate design
Product features are suitable for local circumstances and needs.

### Awareness
Clear and confirmed demand, and necessary policies in place.

**Learnings**: For MAP products focused on the markets of low- and middle-income countries (LMICs), market-shaping strategies will be needed. Dual market potential may increase commercial viability.

**Gaps identified**: Understanding procurers' willingness to pay for MAPs' programmatic advantages will be critical to understanding potential uptake.



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**The Vaccine Innovation Prioritisation Strategy (VIPS)** is a global partnership between the **Gavi Secretariat**, **World Health Organization** (WHO), **United Nations Children's Fund** (UNICEF), **Bill & Melinda Gates Foundation**, and **PATH**— known as the VIPS Alliance—to **prioritise and drive vaccine product innovation** to increase equitable vaccine coverage **in low- and middle-income countries** and contribute to global health security.

# VIPS has prioritised 3 innovations with the broadest public health benefits, that can help better meet country needs & contribute to coverage and equity goals

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

**2018-2020**

## PRIORITISATION

**Current**

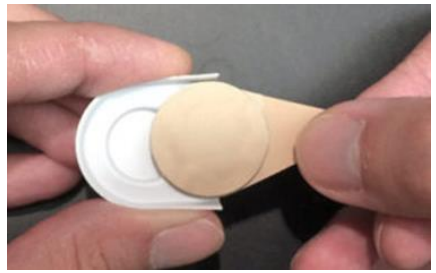
## ACCELERATION

**Long term Impact**

## INCREASED EQUITABLE COVERAGE & PANDEMIC RESPONSE

### Prioritised Innovations

**Microarray patches**



**Heat stable and Controlled Temperature Chain (CTC) qualified vaccines**

**Barcodes on primary packaging**



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

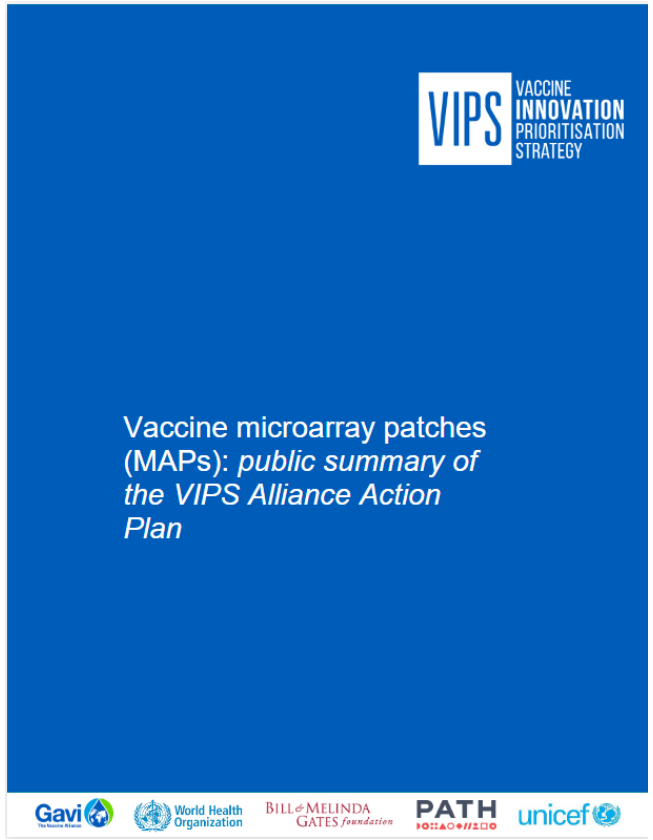
# VIPS Alliance Action Plan

End-to-end, five-year MAP action plan that achieves the following:

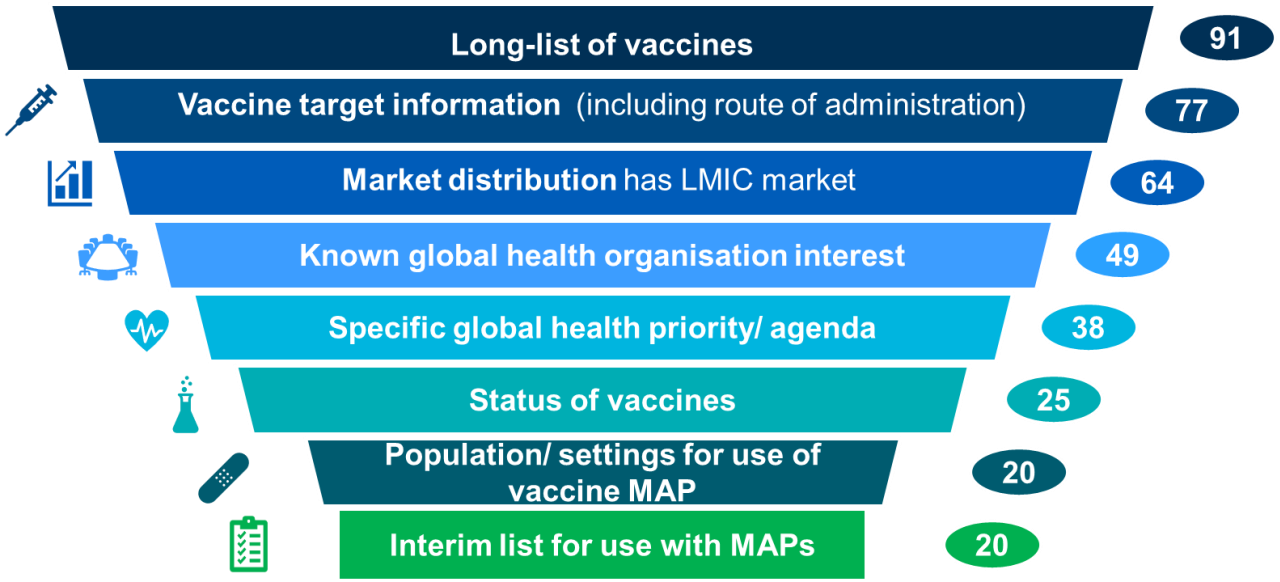
- Identifies activities needed to accelerate the development and future uptake of vaccine MAP products for LMIC use.
- Aspires to advocate for vaccine MAPs in general and attract the interest of other global health partners and funders.

Recent and/or planned VIPS activities include the following:

- Antigen prioritization.
- Cost of goods sold analysis.
- Business models and potential financing mechanisms.
- MAP full vaccine value assessment and country consultations.
- Implementation and policy preparations.



# Proposed priority list of vaccine targets for use with MAPs




VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| | PRIORITY LIST of vaccine targets for MAPs |
|---|---|
| **Priority 1 group** | Hepatitis B virus |
| | Measles-rubella (MR)/measles, mumps, and rubella (MMR) viruses |
| | Human papillomavirus |
| | Rabies virus |
| | Yellow fever |
| | Influenza virus, seasonal and pandemic |
| | SARS-CoV-2 |
| **Priority 2 group** | Group B *Streptococcus* (GBS), *S. agalactiae* |
| | *Neisseria meningitidis* A,C,W,Y,(X) |
| | *Salmonella* Typhi |
| | *Streptococcus pneumoniae* |

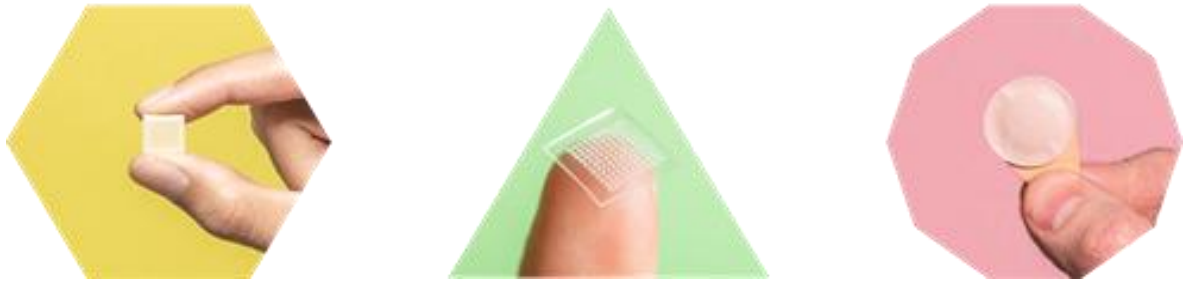


Gavi The Vaccine Alliance · World Health Organization · Bill & Melinda Gates foundation · PATH · unicef

# Question for audience

What other resources
would help facilitate the development
of vaccine MAPs with your antigens?

# Engagement opportunities



**Newsletter**: Please contact MAPs@path.org to be adding to the mailing list.

**MAP Resources page**: For more information on PATH's work on microarray patches, go to https://www.path.org/programs/mdht/mapresources/.

**VIPS site**: For more information on the VIPS Alliance and the technologies, go to https://www.gavi.org/our-alliance/market-shaping/vaccine-innovation-prioritisation-strategy

**Target product profiles**: To review and provide input on MAP target product profiles, go to https://www.path.org/resources/microarray-patch-target-product-profiles-tpp/.

**Regulatory Working Group**: Register your interest in the Regulatory Working Group at http://www.microneedleregulatory.org/.



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# For more information contact:

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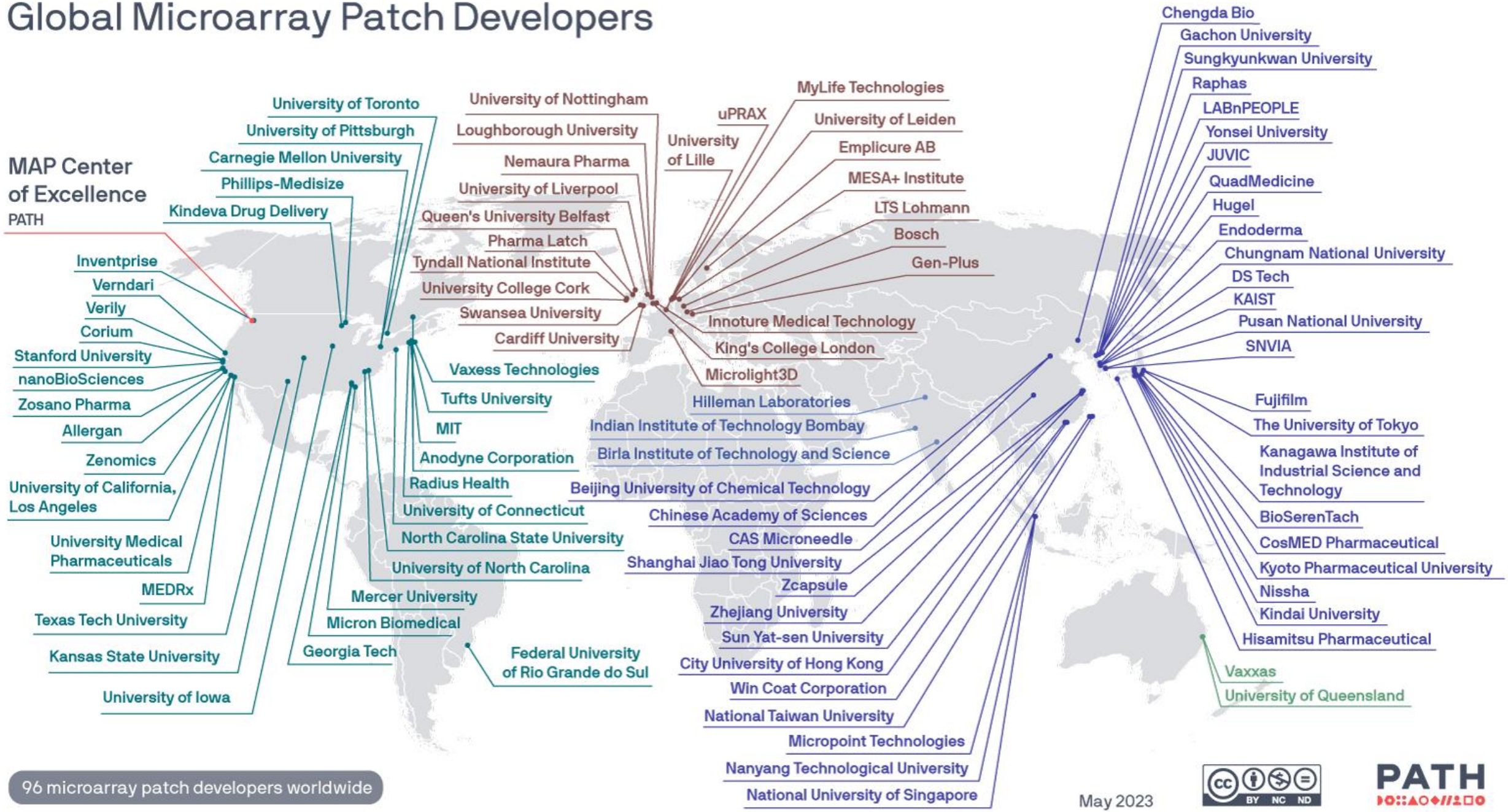
# Appendix

# Global Microarray Patch Developers




96 microarray patch developers worldwide

May 2023



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# Formulation and delivery capabilities at PATH

## Technical design documentation
- Target product profiles
- Product requirement specifications
- User requirements
- Programmatic fit requirements
- Hazard/risk analyses
- Value proposition analyses

## Discovery and research
- Container/delivery device design
- Adjuvant down-selection
- Preclinical support
- Toxicology and immunogenicity

## Drug substance
- Bioanalytical and potency assay development and qualification
- Due diligence and selection of USP/cGMP-grade excipient suppliers/vendors
- Development and qualification of reagents and growth and maintenance cell lines

## Drug product
- Liquid and lyophilized formulation development
- Process scale-up and optimization
- Fill/finish equipment and cost of goods sold (COGS)
- Preservative selection and testing for multidose formulations

## Delivery technologies
- Verification testing
- Delivery performance characterization
- Heuristic evaluation
- Human factors evaluation
- Rapid design and prototyping
- WHO-prequalification support
- COGS and total cost of delivery analyses

## Stability evaluation
- Real-time and accelerated stability studies
- Stability studies for supporting VVM and controlled temperature chain (CTC) selection

## Packaging and labeling
- Secondary packaging configurations
- Cold chain volume analyses
- Primary container label
- Vaccine vial monitors (VVMs)
- Instructions for Use (IFU) development

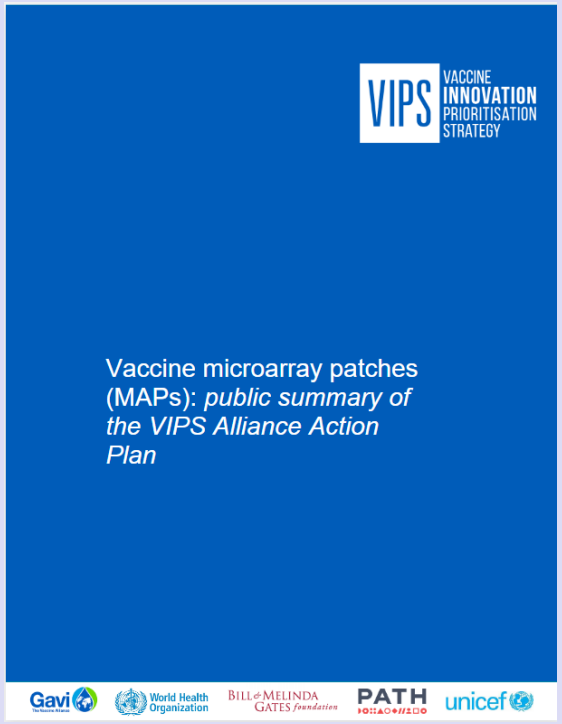
## Clinical studies
- Protocol development and dose verification for clinical study preparations
- Bedside mixing protocol
- Device evaluation
- Acceptability analyses

## General industry support
- Technical guidance specification development
- Market and supply chain landscaping/analyses
- Human-centered design optimization
- Rapid testing and feedback from stakeholders



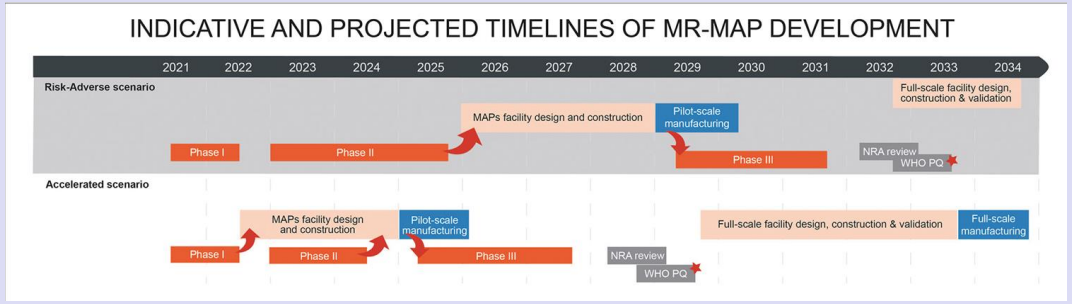
Abbreviations: cGMP, current good manufacturing practices; USP, United States Pharmacopeia; WHO, World Health Organization.

# Engagement and dissemination: Resource examples




[VIPS Alliance Action Plan]


[MAP Resources web page]


[MR MAP: Recent progress, remaining challenges]



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# User needs:
# Resource examples


HPV MAP assessment

**A rabies vaccine MAP** Understanding user and program needs

Rabies vaccine report


User and program-needs brief



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# Technical development: Resource examples


MAP packaging report


Dissolving MAP article


Target product profile

# Manufacturing: Resource examples

EXPERT OPINION ON DRUG DELIVERY
2023, VOL. 20, NO. 3, 315–322
https://doi.org/10.1080/17425247.2023.2168641

Taylor & Francis
Taylor & Francis Group

REVIEW

OPEN ACCESS Check for updates

**Accelerating the development of vaccine microarray patches for epidemic response and equitable immunization coverage requires investment in microarray patch manufacturing facilities**

Tiziana Scarnà[a], Marion Menozzi-Arnaud[a], Martin Friede[b], Kerry DeMarco[c], George Plopper[c], Melinda Hamer[d,e,f], Ajoy Chakrabarti[g], Philippe Alexandre Gilbert[g], Courtney Jarrahian[h], Jessica Mistilis[h], Renske Hesselink[i], Kristoffer Gandrup-Marino[i], Jean-Pierre Amorij[i] and Birgitte Giersing[b]

Manufacturing investment commentary

Drug Delivery and Translational Research (2022) 12:368–375
https://doi.org/10.1007/s13346-021-01076-4

ORIGINAL ARTICLE

Check for updates

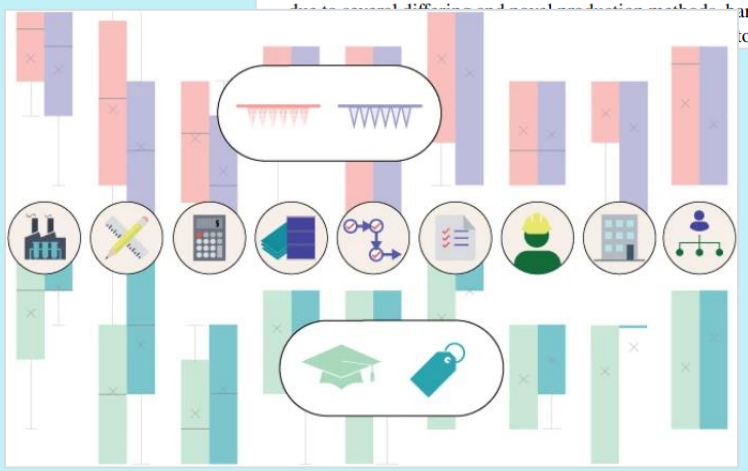
**Manufacturing readiness assessment for evaluation of the microneedle array patch industry: an exploration of barriers to full-scale manufacturing**

Ben Creelman[1] · Collrane Frivold[1] · Sierra Jessup[1] · Gene Saxon[1] · Courtney Jarrahian[1]

Accepted: 3 October 2021 / Published online: 15 October 2021


**Abstract**
Microneedle array patch (MAP) technology is a promising new delivery technology for vaccines and pharmaceuticals, yet
arriers to full-scale manufacturing exist. PATH conducted a manu-
o identify both the current manufacturing readiness of the industry

Manufacturing readiness assessment





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# Regulatory:
# Resource examples

Journal of Controlled Release 361 (2023) 236–245

Contents lists available at ScienceDirect

Journal of Controlled Release

journal homepage: www.elsevier.com/locate/jconrel

Review article

Assessing the risk of a clinically significant infection from a Microneedle Array Patch (MAP) product☆

Maria Dul[a,1], Mohammed Alali[b], Mahmoud Ameri[c,2], Matthew Douglas Burke[d,3], Christine M. Craig[e], Benjamin Paul Creelman[f], Lisa Dick[g], Ryan F. Donnelly[h], Michael N. Eakins[i], Collrane Frivold[f], Angus Harry Forster[j], Philippe-Alexandre Gilbert[k], Stefan Henke[l,4], Sebastien Henry[m], Desmond Hunt[n], Hayley Lewis[o], Howard I. Maibach[p], Jessica Joyce Mistilis[f], Jung-Hwan Park[q], Mark R. Prausnitz[r], David Kenneth Robinson[k], Carmen Amelia Rodriguez Hernandez[b], Charles Ross[j], Juyeop Shin[s], Tycho Joseph Speaker[t], Kevin Michael Taylor[u], Darin Zehrung[v,5,6], James C. Birchall[a,6], Courtney Jarrahian[f,*,6], Sion A. Coulman[a,*,6]

Risk assessment article

MAP RWG

HOME | REGISTER YOUR INTEREST | WHAT IS A MAP? | OUR ACTIVITIES | COLLABORATE | DISSEMINATION | CONTACT US

Microneedle Array Patch Regulatory Working Group

Mission: The Microneedle Array Patch (MAP) Regulatory Working Group (RWG) aims to inform, guide and define the regulatory science of the MAP dosage form.

Scope of work: Our work focusses on the key contemporary CMC-related regulatory issues for MAPs, which are identified by consultation with key stakeholders.

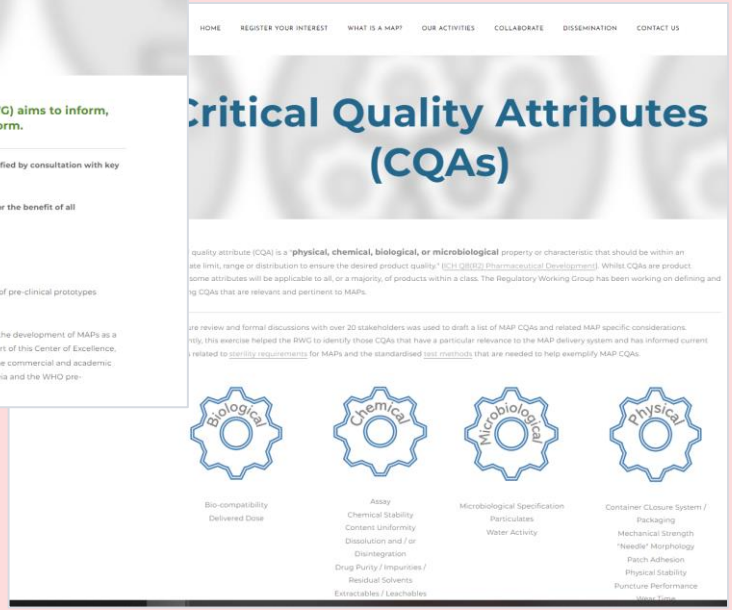
Collaborative working: This is a collaborative endeavour that aims to expedite clinical translation of the technology for the benefit of all stakeholders, including product developers, regulatory authorities, public health bodies and end-users.

Activities: We have parallel work streams that aim to:

(1) define the MAP dosage form
(2) identify and understand MAP critical quality attributes (CQAs)
(3) develop standardised validated test methods to evaluate the quality of finished MAP products and/or the development of pre-clinical prototypes
(4) inform the microbiological requirements for MAP products.

Background: The MAP-RWG was formed as part of the Center of Excellence for MAP technology, an initiative to accelerate the development of MAPs as a technology platform for high-priority needs (vaccines and essential medicines) in low- and middle-income countries. As part of this Center of Excellence, PATH has partnered with Cardiff University to co-Chair a group that includes representatives with MAP expertise in both the commercial and academic sectors, vaccine development experts and representatives from national regulatory authorities, international pharmacopoeia and the WHO pre-qualification of medicines programme.

Regulatory Working Group website



HOME | REGISTER YOUR INTEREST | WHAT IS A MAP? | OUR ACTIVITIES | COLLABORATE | DISSEMINATION | CONTACT US

Critical Quality Attributes (CQAs)

Biological

Bio-compatibility
Delivered Dose

Chemical

Assay
Chemical Stability
Content Uniformity
Dissolution and / or Disintegration
Drug Purity / Impurities / Residual Solvents
Extractables / Leachables

Microbiological

Microbiological Specification
Particulates
Water Activity

Physical

Container CLosure System / Packaging
Mechanical Strength
"Needle" Morphology
Patch Adhesion
Physical Stability
Puncture Performance



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# Business strategy: Resource examples


PLOS GLOBAL PUBLIC HEALTH

RESEARCH ARTICLE

Evaluating the potential cost-effectiveness of microarray patches to expand access to hepatitis B birth dose vaccination in low-and middle-income countries: A modelling study

Christopher P. Seaman[1,2], Mercy Mvundura[3], Collrane Frivold[3], Christopher Morgan[1,4,5], Courtney Jarrahian[3], Jess Howell[1,2,6,7], Margaret Hellard[1,2,8,9], Nick Scott[1,2]*

Cost-effectiveness evaluation


frontiers | Frontiers in Public Health

TYPE Original Research
PUBLISHED 16 January 2023
DOI 10.3389/fpubh.2022.1037157

Check for updates

OPEN ACCESS

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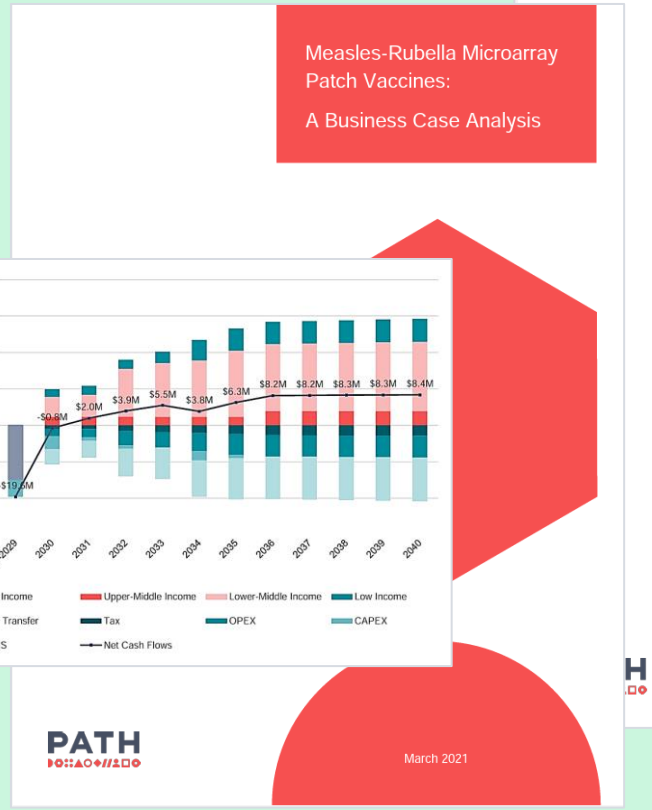
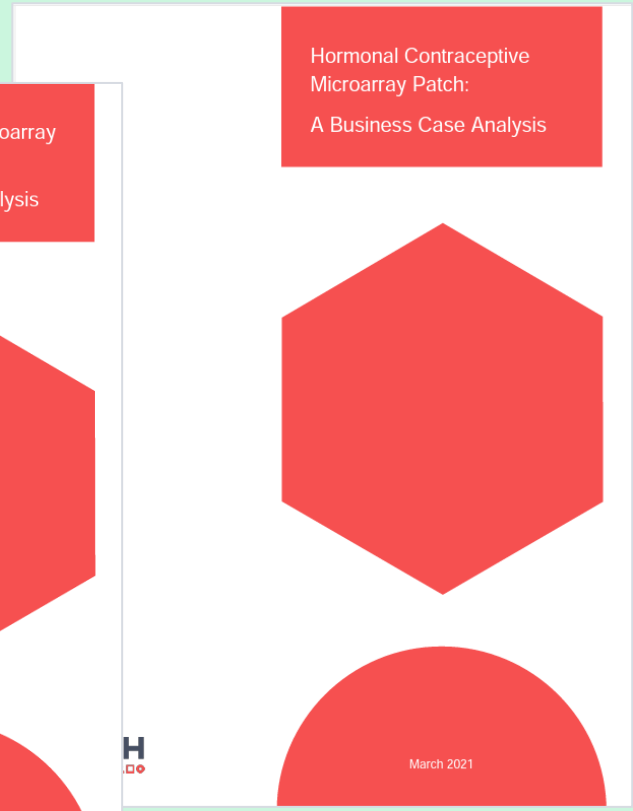
Estimating the future global dose demand for measles–rubella microarray patches

Melissa Ko[1]*, Stefano Malvolti[2], Thomas Cherian[1], Carsten Mantel[2], Robin Biellik[3], Courtney Jarrahian[4], Marion Menozzi-Arnaud[5], Jean-Pierre Amorij[6], Hans Christiansen[6], Mark J. Papania[7], Martin I. Meltzer[8], Balcha Girma Masresha[9], Desiree Pastor[10], David N. Durrheim[11], Birgitte Giersing[12] and Mateusz Hasso-Agopsowicz[12]*

MR MAP future-demand evaluation




MR MAP business case




Contraceptive MAP business case



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