VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

UNICEF 2023 VACCINE INDUSTRY CONSULTATION

Vaccine Innovation Prioritisation Strategy Update

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VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

Micro-array patches update

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Since we presented the VIPS priority list of vaccine targets for MAPs last year, a lot of progress in particular for MR-MAPs

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	Priority list of vaccine targets for MAPs
Priority 1 group	Hepatitis B virus
	Measles, rubella (MR)/ Measles, mumps and rubella (MMR) viruses[1]
	Human papillomavirus
	Rabies virus
	Yellow fever
	Influenza virus, seasonal and pandemic
	SARS-CoV-2[2]
Priority 2 group	Group B streptococcus (GBS), S agalactiae
	Neisseria meningitidis A,C,W,Y,(X)
	Salmonella Typhi
	Streptococcus pneumoniae[3]

1 https://www.prnewswire.com/news-releases/micron-biomedical-announces-positive-measles-and-rubella-vaccination-results-from-first-clinical-trial-of-microarray-injection-free-vaccine-delivery-in-children-301826746.html
2 https://www.businesswire.com/news/home/20230605005248/en/Vaxxas-Announces-Interim-Results-from-Phase-I-Clinical-Study-of-First-Needle-Free-COVID-19-Vaccine-Delivered-Using-Proprietary-High-Density-Microarray-Patch-HD-MAP
3 https://www.vaxxas.com/news/articles/vaxxas-awarded-usd3.67-million-aud5.4-million-from-global-charitable-foundation-wellcome-for-human-clinical-study-of-typhoid-vaccination-using-needle-free-vaccine-patch/

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4 CTC qualified products are on the market & VIPS has identified 5 additional priority antigens for CTC use

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2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 & beyond

MenAfri Vac (MenA) 4 days

Prevnar (PCV)

Gardasil (HPV) 3 days

Shanchol (OCV) 14 days

Typbar (TCV) 7 days

Updated PQ of Gardasil and new PQ of **Gardasil9** for CTC use up to **4 days** (HPV)

CTC Qualified Vaccines

Additional antigens included in VIPS CTC PRIORITY LIST

- **dT** (reduced d antigen for adults/adolescents)
- **Hepatitis B (birth dose)**
- **Measles-Rubella (MR)-MAP**[1]
- **Meningitis A,C, W, Y (X)**
- **SARS-COV-2**

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[1] *MR-MAP is included here due to the stage of development and the thermostability data available, but all other vaccines prioritised under the vaccine MAPs prioritisation exercise would be targets for CTC*

First clinical proof of concept in infants for micro-array patches (MAPs)

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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-months old** with a **MAP for measles rubella (MR-MAP)** from Micron 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 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 that the **MAP technology would be better than SC injection.**

MR-MAPs could reduce measles burden by 35% and reach 80 million more children between 2030 and 2040

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Reduction in measles

CASES

by up to **37** million cases

35% reduction

Reduction in measles

DEATHS

by up to **397** Thousand deaths

35% reduction

Reduction in measles-related

DALYs lost

by up to **26** million DALYs

35% reduction

MR-MAPs could reach an estimated 80-110 million more children (8-11%) between 2030 and 2040 than would be reached using needle and syringe presentation alone

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Source: MR-MAPs initial Full Value of Vaccine Assessment - UNICEF

MR-MAPs procurement may require investment per DALY saved similar to that of other vaccines

IFVVA modeling* demonstrates that **cost per DALY saved for LICs and LMICs for MR-MAPs ($85-$2,310) is comparable to HPV ($91-$928), Rotavirus ($202-$428) and RSV maternal vaccines ($70-$270).**

*Estimated doses from MR-MAP demand forecasting, estimated price from benchmarking analysis, and estimated DALYs from DynaMICE

Source: MR-MAPs initial Full Value of Vaccine Assessment - UNICEF

PATH is generating data on both the Micron and Vaxxas MR MAPs to inform advancement to Phase 3 clinical research

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Phase 2 Clinical Trials

Two separate randomized, controlled Phase 2 clinical trials to assess safety/tolerability and immunogenicity of each MR MAP compared to standard-of-care MR needle-syringe delivery

Human Factors Evaluation

Usability, acceptability, and programmatic fit data in target user populations in Democratic Republic of the Congo, Nepal, and Kenya

Thermostability Study

Evaluation of MR MAPs in a 24-month stability study, including controlled temperature chain (CTC) and vaccine vial monitor (VVM) compatibility

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

User testing MAP prototypes in Kenya.

Pre-test learnings focused on training requirements, refining the instructions for use, identifying user errors, and recommendations on attributes for programmatic feasibility.

8

Use cases for MR-MAPs have been defined through extensive consultations with countries

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	1	2	3-4
Use Cases	**Delivery in a fixed post by health care worker or community health care worker**	**Outreach delivery by health care worker**	**Outreach or campaign delivery by community health care worker**
Immunisation barriers addressed	• **Vaccine hesitancy** as no fear of needle and no pain • **Missed opportunities for vaccination** as single dose presentation and one less injection for co-delivery with other antigens	+ • **Logistical limitations** as more thermostable (CTC/ VVM30) and light **and reducing wastage** as single-dose presentation	+ • **Limited trained personnel** as ease of use enables delivery by lesser trained health care worker and ability of community health care workers to reach remote areas

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Workshops conducted by WHO on MR-MAPs conducted in several LMICs show high interest

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Would you introduce MR-MAPs?

Ethiopia[1]	*"We would consider a **full switch to MR-MAPs for routine immunization and campaigns with phased uptake** based on equity considerations and availability"*
Guyana and Caribbean[2]	*"**MR-MAPs** could enable us to **sustain our elimination status** as we would **use them to immunise very hard to reach and highly mobile populations"***
Indonesia[3]	***"Pilot introduction** would inform a phased approach for a broader introduction of **MR-MAPs**"*
Uganda[4]	*"A full switch would greatly simplify **MR-MAPs** implementation that would be **most beneficial** to reach populations living in **urban slums, refugees, people living in mountainous areas or islands and nomadic populations "***

1. 44 **participants** from: MOH, EPHI, Regional Advisors, WHO HQ, RO, CO, USAID, Project Hope, Addis Ababa University, CHAI, UNICEF, PATH, EFDA
2. **54 participants** from: Representatives from Guyana, Suriname, Belize, Jamaica, Trinidad and Tobago, Barbados, including Ministry of Health, NITAG, Interagency Coordination Committee, Nurses, EPI Supervisors, cold chain advisor, vaccine safety, regional commission for measles elimination, Revolving Fund, The Caribbean Public Health Agency (CARPHA), WHO/PAHO
3. **49 Participants** from: MOH, CDC Indonesia, ITAGI, Indonesian FDA (Badan POM), Pharmaceutical Resilience, WHO HQ, CO, UNICEF
4. **55 Participants** from: MOH, EPHI, Regional Advisors, WHO HQ, RO, CO, CHAI, UNICEF, PATH, Gavi

Global demand for MR-MAPs has been estimated for each of the use cases

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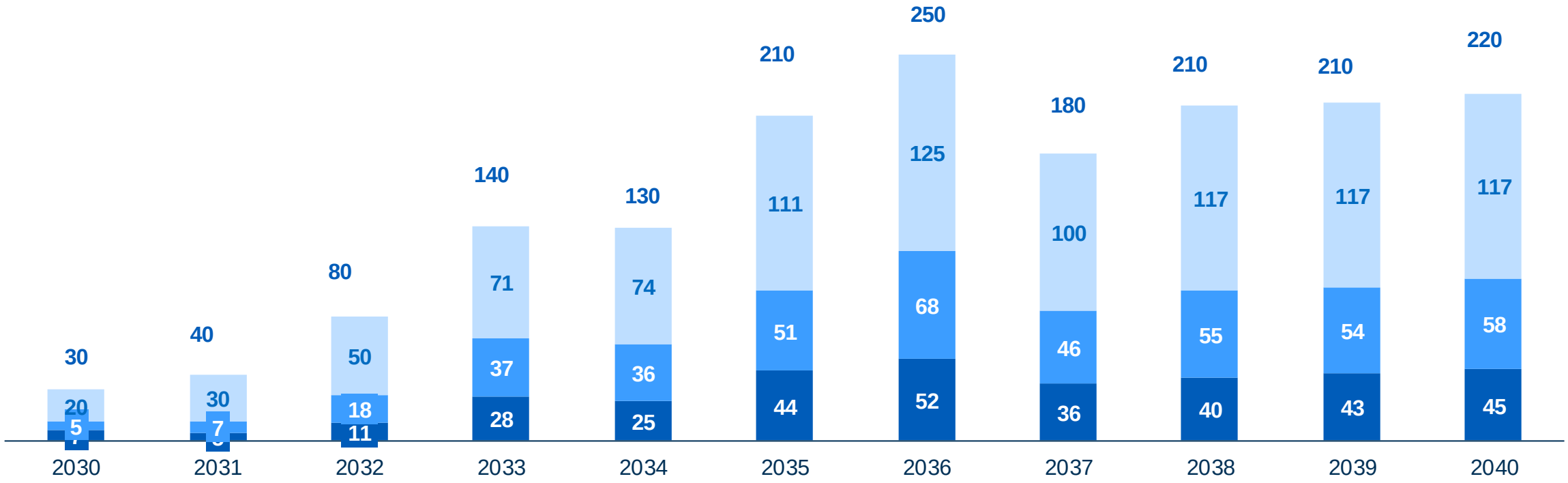
MR-MAPs global demand scenarios needs (# of doses, million)

UC 1	Delivery in a fixed post by health care worker or community health care worker
UC 2	Outreach delivery by health care worker
UC 3-4	Outreach or campaign delivery by community health care worker



Source: MR-MAPs global demand estimate - WHO

A market incentive could contribute to ensure MR-MAP availability by 2030

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Goal

Get a **first vaccine-MAP available for LMICs by 2030**

Mechanism

Demand guarantee corresponding to initial demand based on level of ambition, contingent on a few conditions

Outcome

Reduce demand risk and incentivize a partner to commit to MR-MAPs soon

Initial thinking

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Heat-stable and Controlled Temperature Chain (CTC) qualified vaccines update

VIPS has developed a strategic roadmap to identify key opportunities to accelerate CTC development & adoption

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LONG-TERM VISION

To enable qualification and CTC use of vaccines where impactful, to overcome country immunisation barriers and ensure equitable access to vaccines

TO* 1: Impact of CTC is demonstrated via generation of evidence to enable future decision-making

TO 2: **Value proposition of CTC** is clearly defined and communicated

TO 3: Industry is incentivised to develop priority CTC vaccines through an enabling environment

TO4: Country demand for CTC is generated and **adequate support** is provided to introduce and **use sustainably**, beyond pilot introductions

Current VIPS focus is on generating evidence on the impact of CTC – especially on improving coverage, equity and campaign efficiency. Two research studies with HPV and TCV[1] will be used to generate evidence - planning underway to conduct studies in selected countries in 2024-25.

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* TO: Target Outcome; [1]Evidence on impact is also anticipated for OCV, generated through GTFCC's research agenda.

In the meantime, VIPS will pursue other opportunities like Hep B BD to support development and adoption of CTC

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Deep-dive on Hep B Birth Dose

- Gavi has recently **'unpaused' VIS 2018 vaccines** including Hep B birth dose with 6.0 ambition to target **out of facility births**.
- Use of CTC can help reach such remote home-births, with **strong evidence of impact** seen with current experiences **out of cold chain**.

1. **Use in Laos (2016)**
Non-random comparison trial showed **27% increase in coverage**

2. **Solomon Islands trial** (2017)
Timely BD **coverage** increased from **30-68%** in facilities and from **4-24%** in home births

3. **Cost effectiveness study across 72 countries (2018)**
Mathematical modelling showed CTC outreach strategy is likely to be **cost-saving.**

Currently Hep B birth dose vaccines are not CTC qualified but some vaccines potentially have the required thermostability to be CTC qualified. **We encourage Hep B BD manufacturers to explore CTC qualification for their vaccines and to reach out to VIPS partners for further engagement if needed.**

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Sources in speakers notes

On thermostable vaccines, VIPS is currently aiming to understand specific country needs before moving forward

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Heat-stable vaccines

- Refers to **improvement in long-term storage** of vaccines, including shelf-life, e.g., to the following stability targets:
  a. From **ultra cold-chain** to **2-8C**
  b. From -**20C** to **2-8C**
  c. From VVM7 or VVM14 to VVM30
- In order to achieve these improvements, **reformulation** and/or other novel/ complex thermostabilisation methods may be needed.

VIPS focus

Targeted country consultations ongoing

- With cold-chain/ supply chain experts, vaccine program managers and EPI managers at national, regional and local levels
- To understand the **incremental thermostability improvements** needed and **acceptable trade-offs**
- via **survey** and **in-depth interviews**

Interested manufacturers working on thermostability improvements are invited to let us know if you have insights / data on these themes that you can share with VIPS.

BARCODES ON VACCINE PRODUCTS

VIPS activities on barcodes have focused on extensive consultations to develop a partner-aligned roadmap

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

Extensive consultations

COUNTRY CONSULTATIONS
>80 interviews with **15** countries (incl. 2 HICs)

VACCINE MANUFACTURERs
~5 across HIC & LMIC markets

GS1, SUPPLY-CHAIN & REGULATORY EXPERTS
~8 interviews

DONOR AGENCIES
5 interviews

Alliance partners closely involved

Gavi The Vaccine Alliance
Market Shaping & **HSIS** teams

unicef
Vaccine Centre and **Supply Chain Strengthening** Centre

World Health Organization
MHP & **IVB**

PATH
Living Labs

Additional donor/partner buy-in

- BMGF
- USAID
- The Global Fund
- PAHO

Ongoing

Countries and manufacturers consulted see clear benefits of barcodes on secondary packaging and feasibility to implement

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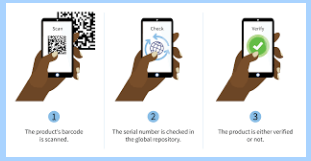
5 USE CASES PRIORITISED based on country and expert consultations

1. Automate **stock and inventory management**

2. Facilitate targeted **product recalls**



3. Verify **authenticity**

4. Link vaccine information with **patient records**

5. Facilitate reporting of **adverse events**

Countries and manufacturers consulted prioritise barcodes on secondary packaging

Secondary packaging


Barcode on secondary packaging

Both countries and manufacturers see **clear value** in using barcodes and implementation is seen as **feasible,** but needs systems, processes & policies to ensure sustainable adoption.

Primary packaging

Both countries and manufacturers cite **perceived complexity & costs** of adding & using barcodes on vials. Priority is to increase utilization of secondary packaging first and generate evidence on primary packaging.

The barcodes roadmap identifies a long-term vision and short-term objectives to accelerate barcodes adoption in LMICs

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

LONG-TERM VISION

Enhance **health system digitalisation** through the use of barcodes to ensure **equitable coverage** and **improve program efficiency** in LMICs.

SHORT-TERM OBJECTIVES (2024-2026)

A **DEMONSTRATE IMPACT** of barcodes on **secondary packaging** to achieve the LT vision and incentivize investment for scale-up

B **Create an enabling environment** for further scale up of barcodes *(e.g., traceability systems, policies, hardware, software and human resources)*

C Where opportunities exist, **generate evidence on barcoded primary packaging to inform potential future activities.**

Targeted implementation of barcodes in advanced LMICs will enable to demonstrate impact/feasibility and needs to inform future scale-up

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

SHORT-TERM OBJECTIVES (2024-2026)

A **DEMONSTRATE IMPACT** of barcodes on **secondary packaging** to achieve the LT vision and incentivize investment for scale-up

Key activity planned: Targeted implementation of barcodes (secondary) in ~3-4 advanced LMICs at a national/ regional scale in 2024-25

- Demonstrate barcodes **impact** on equitable coverage and program efficiency and understand **feasibility** in LMICs – to **incentivise** countries, donors and manufacturers
- Identify **best practices** – to inform **future scale-up**
- Understand **total cost of ownership** – to inform future **investment case**

Implications for Vaccine Manufacturers:

- Scope for targeted implementation will include vaccines with **serialised barcodes on secondary packaging** to enable all use cases.
- Aligned with long-term needs for vaccine supply – to ensure **barcodes with serialised and aggregated data**.

Barcodes alone cannot ensure full traceability; an enabling environment with multiple systems and processes is needed

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SHORT-TERM OBJECTIVES (2024-2026)

Key initiatives ongoing/ planned:

- Gavi's **eLMIS scale-up strategy** focusing on at least 25 priority countries by 2025
- **TRVST pilots** conducted in 2 countries and planned in at least 4 other countries.
- Many countries have invested in **traceability strategy development**
- Activities to **harmonize global guidance** on labelling standards, product identification and data exchange

More investments needed to integrate barcodes moving forward.

B

Create an enabling environment for further scale up of barcodes *(e.g., traceability systems, policies, hardware, software and human resources)*

Implications for Vaccine Manufacturers:

Barcodes-encoded data will be needed **via the required data repository** to enable countries to effectively use the data for the use cases as products move across the supply chain.

On primary packaging, the goal is to be opportunistic and leverage the targeted implementations to generate evidence where possible

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SHORT-TERM OBJECTIVES (2024-2026)

Key activity planned on primary packaging:

- If feasible, leverage the **targeted implementations** to also **investigate benefits of barcodes on primary packaging** (i.e., benefits, system requirements, cost effectiveness, feasibility and scalability).
- Based on study results determine future activities on primary packaging.

C

Where opportunities exist, **generate evidence on primary packaging to inform potential future activities.**

Implications for Vaccine Manufacturers:

- Manufacturers producing/planning to produce **vaccines with barcodes on primary packaging** and interested to participate in targeted implementation projects are invited to contact us.
- Please also reach out to exchange insights / lessons learned related to barcode implementation on vials.

The VIPS barcodes public roadmap will be published in coming months

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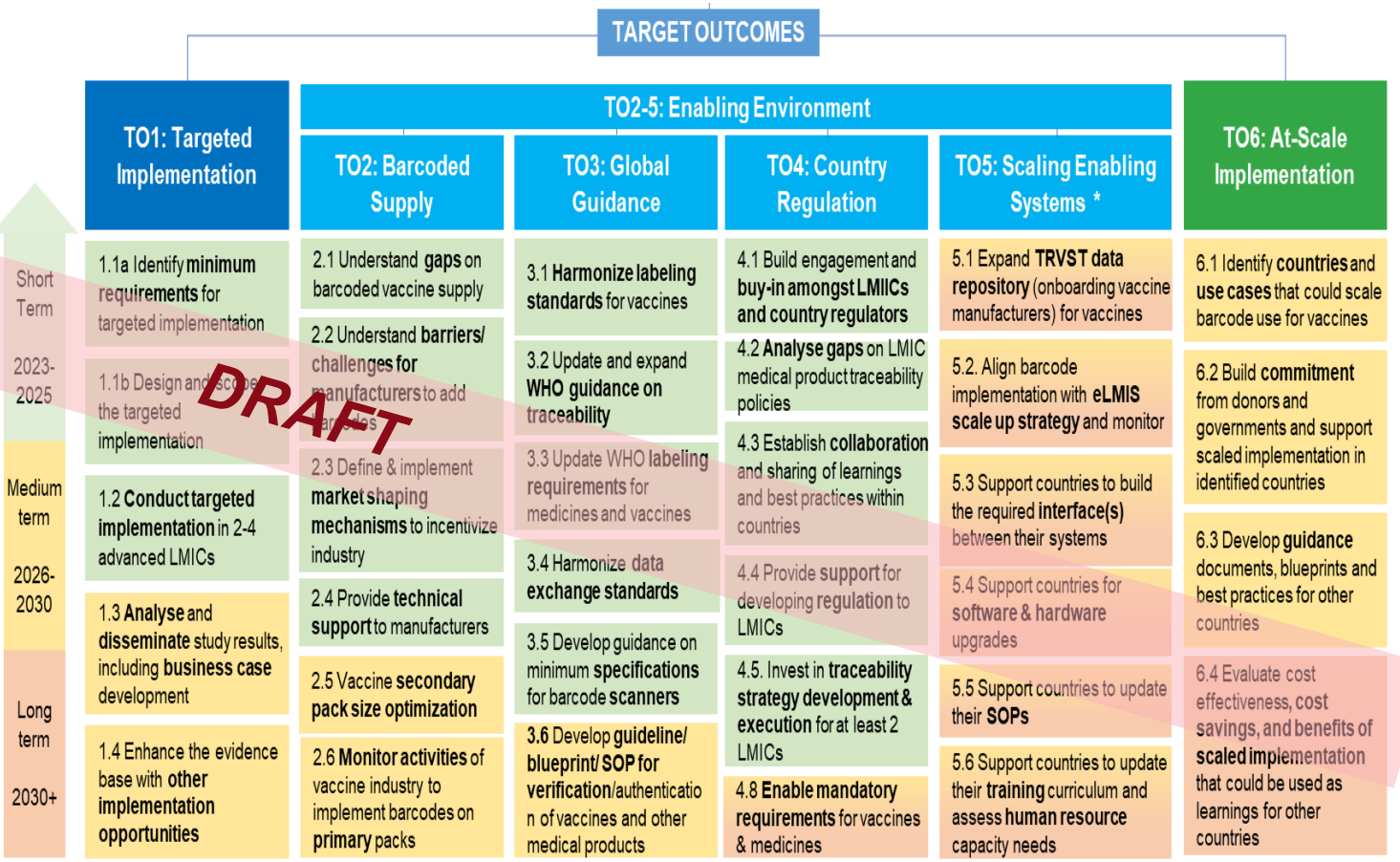
BARCODES ON VACCINE PRODUCTS
VIPS Alliance Roadmap



** Timelines for scale up of enabling systems are dependent on country readiness & maturity; for advanced countries, the aim is to scale up remaining systems in the short-med term while for less advanced countries this will occur in the med-long term.*

Contact information - for questions or feedback

Please contact VIPS leads:

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- Jean-Pierre Amorij, UNICEF: jamorij@unicef.org

VIPS webpage:

https://www.gavi.org/our-alliance/market-shaping/vaccine-innovation-prioritisation-strategy