VIPS - Vaccine Innovation Prioritisation Strategy

(focusing on vaccine product attributes)

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Presentation objectives

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

- To introduce the Vaccine Innovation Prioritisation Strategy (VIPS) initiative to DCVMN members, in preparation for a plenary session on VIPS at the annual General Meeting, in October 2019.

VIPS: Vision and goal

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VISION

- **Innovation** is one of the **Alliance priorities** for shaping markets to the benefit of Gavi-supported countries.
- The Alliance aims to pursue a common agenda of:
  - **Driving vaccine product innovation to better meet country needs**
  - **Support Alliance goals on immunisation coverage and equity.**

GOAL

- **Prioritise innovations in vaccine product attributes to provide greater clarity to manufacturers and partners to make investment decisions.**

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What do we mean by product innovation

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Driving **product innovation** to better meet **country needs** and improve **coverage and equity**

Definition:

The term ‘product innovation’ refers to **completely new products** or to **adaptations to existing products** that provide **measurable financial or programmatic benefits** to **lower and middle income countries**, such as increased coverage and equity (e.g., by overcoming a ‘last mile’ barrier) or vaccine effectiveness.

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VIPS is a close Alliance-wide collaboration effort

VIPS also relies on a Steering Committee: an independent and expert advisory body

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

17 experts bring the following expertise:

- **National immunisation programme** financing and implementation
- **Coverage and equity** barriers and challenges
- Infectious disease **epidemiology** / **vaccine-preventable disease control**
- **Health impact analysis** / modelling
- **Vaccine** innovations, **R&D**, upstream product development.

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VIPS will assess 24 vaccine delivery related innovations

Category	Innovation type
Primary vaccine container (w/o delivery device)	Blow-fill-seal (BFS) primary containers
	Dual chamber vials
Integrated primary container and delivery technology	Compact prefilled auto-disable devices (CPAD)
	Single-chamber cartridge injectors
	Dual-chamber delivery devices
	Microarray patches (MAP)
	Prefilled polymer BFS dropper/dispensers
	Prefilled dry-powder intranasal devices
	Solid-dose implants (w/ applicator)
	Sub-lingual dosage forms
	Oral fast-dissolving tablets

Category	Innovation type
Delivery technology (not pre-filled)	AD sharps-injury protection (SIP) syringes
	Disposable syringe jet injectors (DSJI)
	ID syringes
Formulation	Heat stable/controlled temperature chain (CTC) qualified liquid formulations
	Heat stable/ CTC qualified dry formulations
	Freeze damage resistant liquid formulations
Packaging and safety	Bundling devices
	Reconstitution vial adapters
	Plastic needles (for reconstitution)
Labelling	Freeze indicator on primary vaccine container
	Combined Vaccine vial Monitor (VVM) and Threshold Indicator (TI)
	Barcodes
	Radio Frequency Identification (RFID)

VIPS includes two phases

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

Phase I – Initial prioritisation of innovations

From December 2018 to June 2019

Innovations will be analysed in terms of:

- Their **characteristics and potential public health value;**
- Their **potential 'breadth of use'** (applicability to several antigens) based on technical feasibility.

Phase II – Final prioritisation of innovations paired with antigens

From July 2019 to December 2019

- Innovations prioritized in Phase I will be combined with **selected antigens** for **further detailed analyses and prioritisation**.

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Overall prioritisation ‘aim’

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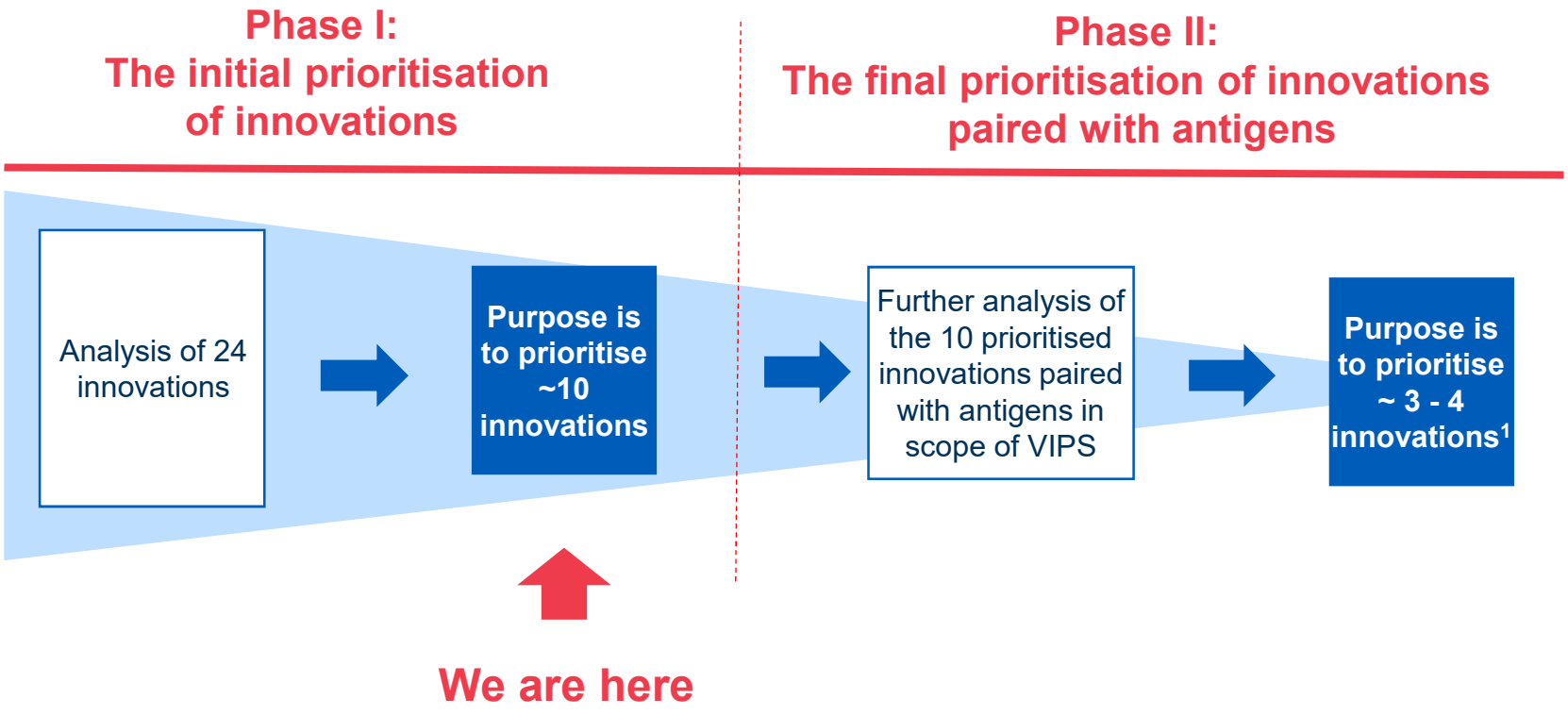

[1] Purpose is to prioritise innovations “themselves”, “as platforms”, however if relevant it will be signaled for which individual antigens/vaccines or types of vaccines the innovation is seen to be most valuable.

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VIPS evaluation framework includes different and complementary indicators for Phase I and Phase II

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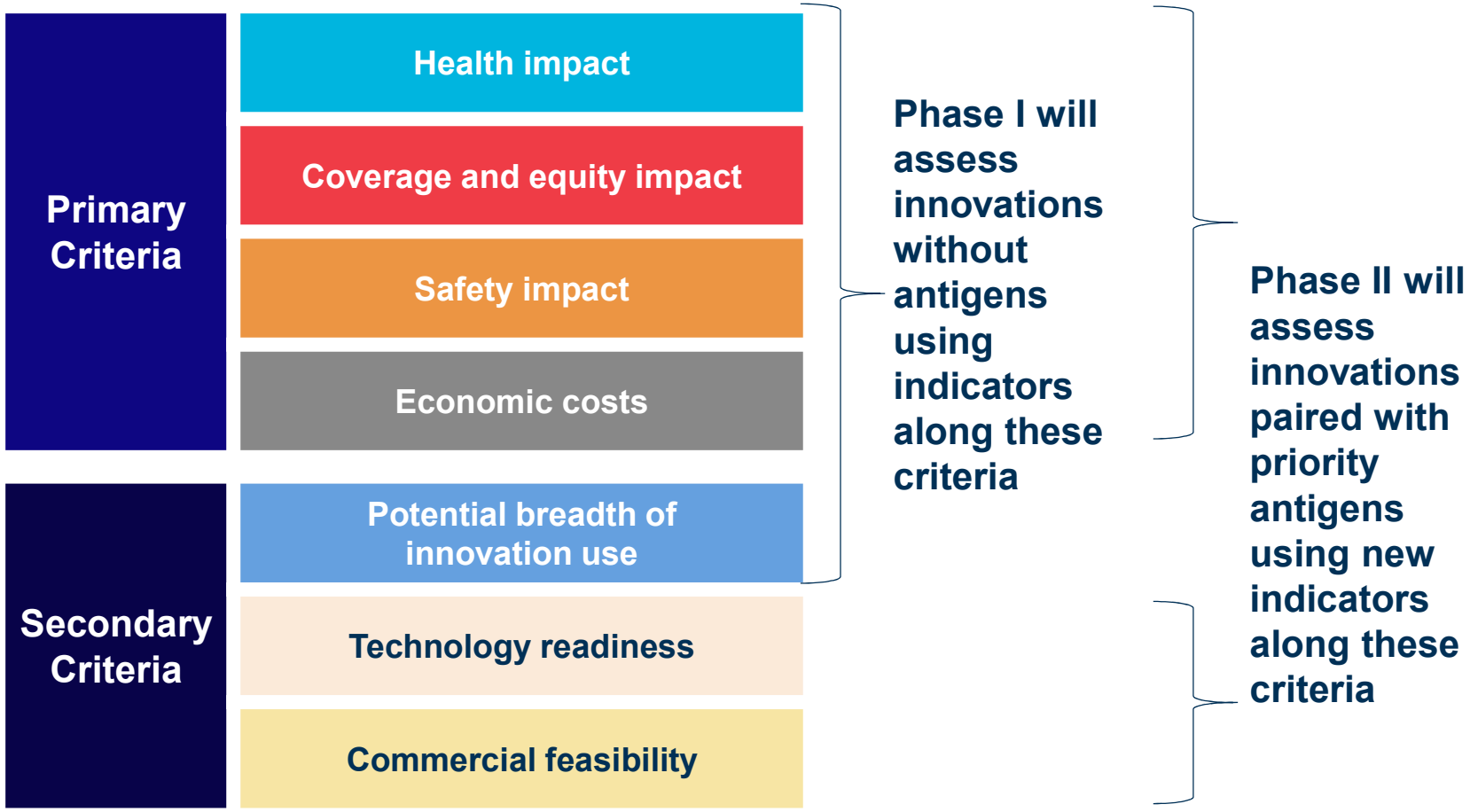

Evaluation framework for Phase I

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

	Criteria	Indicators
Primary ranking criteria	Health Impact	• Ability of the innovation to withstand **heat exposure** • Ability of the innovation to withstand **freeze exposure**
	Coverage and Equity impact	• **Ease of use** • Potential to reduce **stock outs** based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities • **Acceptability** of the innovation to patients/caregivers
	Safety impact	• Likelihood of **contamination** • Likelihood of **needle-stick injury**
	Economic costs *(i.e. Delivery and Introduction and recurrent costs)*	• Total **cost of storage and transport** of commodities per dose • Total **cost of the time spent by staff** per dose • Total **cost of introduction and recurrent costs** (not otherwise accounted for)
Secondary criteria	Potential breadth of innovation use	• Applicability of the innovation to **one or several types of vaccines** • Ability of the innovation to facilitate **novel vaccine combination**

Evaluation framework for Phase II (1/2)

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

	Criteria	Indicators
Primary ranking criteria	**Health Impact**	• Vaccine **efficacy** • Vaccine **effectiveness** • Ability of the innovation to withstand heat exposure[1] • Ability of the innovation to withstand freeze exposure[1]
	Coverage and equity impact	• Number of fully or partially **immunised individuals** (relative to target pop) • Ease of use[2] • Presentation which helps prevent **missed opportunities due to reluctance to open MDV without preservative**
	Safety impact	• Number of vaccine product-related **adverse events** • Likelihood of contamination[2]
	Economic costs *(i.e. Commodity, Delivery and Introduction and recurrent costs)*	• Total **cost of a vaccine regimen with the innovation**, including wastage • Total **cost of delivery technology(ies)** used for the vaccine regimen, including wastage • Total **cost of safety boxes** used for the vaccine regimen, incl wastage • Total cost of storage and transport of commodities (per vaccine regimen)[1] • Total cost of the time spent by staff (per vaccine regimen)[1] • Total cost of introduction and recurrent costs (not otherwise accounted for)[1]

[1] Same indicators as for Phase I but further assessed under Phase II due to the antigen/vaccine pairing

[2] This indicator is re-assessed in Phase II only when the comparator for a specific vaccine is a MDV, requiring a new evaluation – The comparator SDV is assessed in Phase I

Evaluation framework for Phase II (2/2)

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

	Criteria	Indicators
Secondary ranking criteria[1]	**Technology readiness**	• **Clinical development** pathway complexity • **Technology development** challenges • **Regulatory** pathway complexity • Complexity of **manufacturing** the innovation • Robustness of the innovation **pipeline**
	Commercial feasibility	• Potential breadth of **market size** • Existence of **partnerships** to support development and commercialisation • Known **barriers to global access** to the innovation • **Stakeholders' interest**

[1] These criteria will be evaluated in an absolute manner, not relative to a comparator.

In Phase II, the ~ 10 prioritised innovations in Phase I will be further analysed with 17 antigens (10 licensed, 7 pipeline)

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS priority antigens – LICENSED antigen/ vaccine or family of vaccines
Men Vaccines
M or R containing
DT containing
Hepatitis B (birth dose)
Human papillomavirus (HPV)
Poliovirus, inactivated (IPV)
Rabies
Rotavirus
Typhoid (Salmonella typhii),
Yellow Fever (YF)

VIPS priority antigens – PIPELINE specific candidate identified for each antigen
Enterotoxigenic E coli (ETEC)
Ebola
Human immunodeficiency virus (HIV)
Influenza (pandemic)
Mycobacterium tuberculosis (next generation)
Respiratory syncitial virus (RSV)
Malaria (RTS,S & next generation)

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Selection criteria for the VIPS priority antigens

These 17 antigens have been selected based on several criteria, including:

- For **existing vaccines**, preferentially select those that are **WHO PQ'd, GAVI funded and UNICEF procured**
- Prioritize antigens that have an **elimination or eradication agenda**
- Pathogens likely to cause an outbreak, target atypical population, benefit from dose sparing
- Standard multi-dose vial w/ preservative not feasible
- Prioritize antigens that have **a robust pipeline or number of producers** (both for prelicensed and licensed vaccines)
- Unique delivery considerations, e.g. HepB: 40% of deliveries are outside of health facility, by community volunteers.
- For pipeline, select the most advanced, with highest probability of success

Prioritization of pipeline (unlicensed vaccine) candidates

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

Antigen	Vaccine candidate	Platform	Phase	Rationale for inclusion	Reference
Malaria	RTS,S	Adjuvanted recombinant protein (ARP)	IV	Potential for inclusion of fractional dose in schedule (currently 4 doses)	NCT03806465
Ebola	rVSV-ZEBOV	viral vector	compassionate use	Requires storage at -80°C	https://www.who.int/ebola/drc-2018/faq-vaccine/en/
Human immunodeficiency virus (HIV)	P5: ALVAC/ gp120 + MF59	viral vector + ARP	IIb/III	Heterologous prime boost approach, requiring 2 different vaccines in the same regimen	NCT02968849
Influenza (pandemic)	VAL-506440	lipid nanoparticle (LNP)-formulated, modified mRNA	I	Novel vaccination platform with applicability to emergency response pathogens	NCT03076385
Mycobacterium tuberculosis	VPM1002	recombinant BCG	II/III	New generation BCG approaches in late stage clinical development still require ID administration	NCT03152903
Respiratory syncitial virus (RSV)	ResVax	ARP	III	Potential for near term licensure; use of mapping innovations that could facilitate delivery in LMICs	NCT02624947
Enterotoxigenic E coli (ETEC)	Etvax	Inactivatedwhole cell + adjuvant	IIb	Complex formulation, including multiple components	EUCTR2016-002690-35-FI

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Distribution of selected antigens within the vaccine landscape

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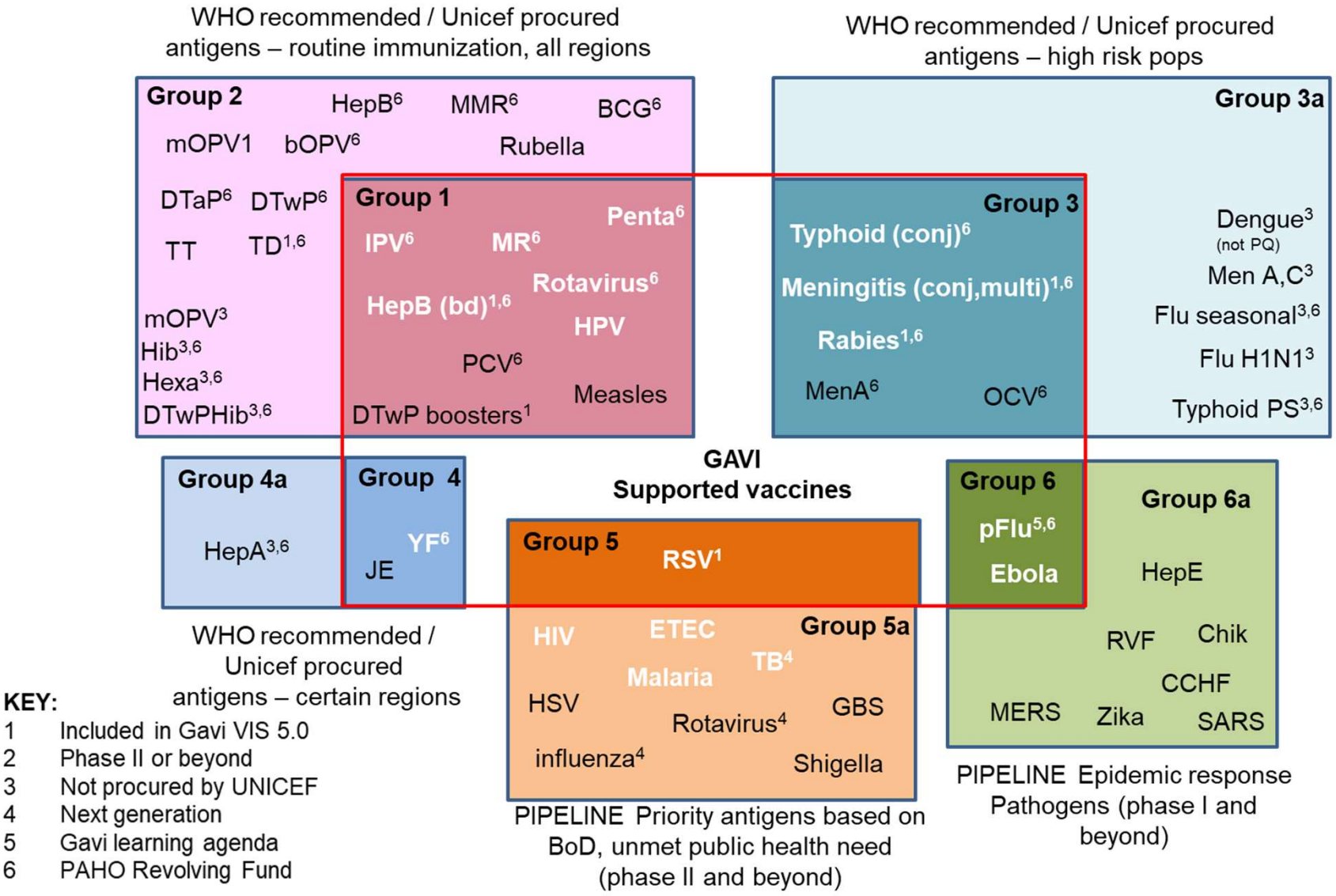

The VIPS team will engage with industry and other key stakeholders

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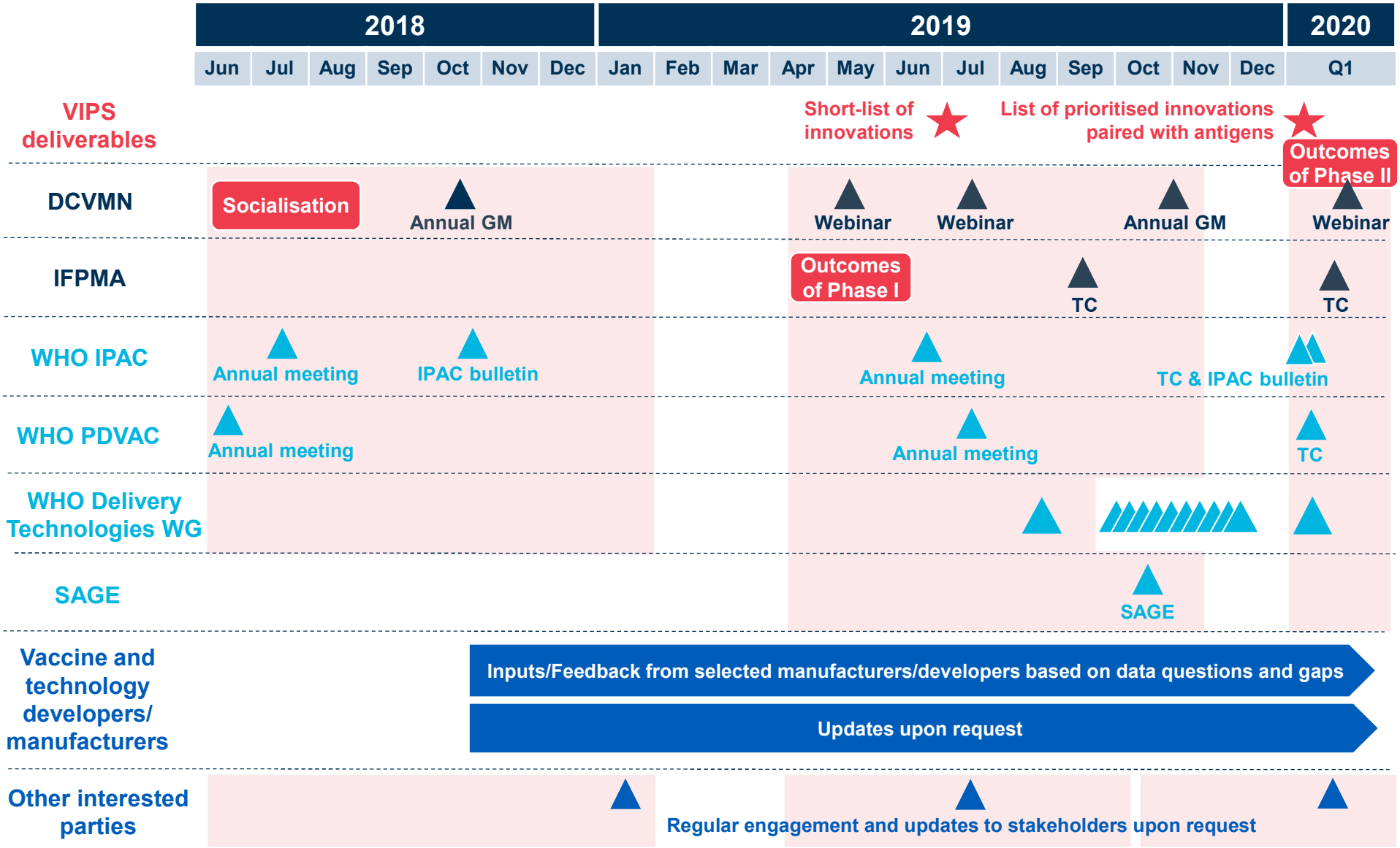


Remit of the WHO/PATH Delivery Technologies Working Group

- Provide a platform to enable **industry and the public sector to engage** in constructive dialogue on the **presentation, packaging, and delivery aspects** of vaccine products.
- Optimize innovation and **maximize the appropriateness of immunization products** for public sector use.

Objectives:

- Inform industry about LMIC programmatic preferences and operational realities.
- Sensitize the public sector to industry constraints and economic realities of investing in product development

VIPS engagement with Delivery Technologies Working Group

- The VIPS team will engage with the DT-WG under Phase II with the objectives to:

  - Update broader set of immunization stakeholders, **including industry,** on VIPS objectives, process, and progress.

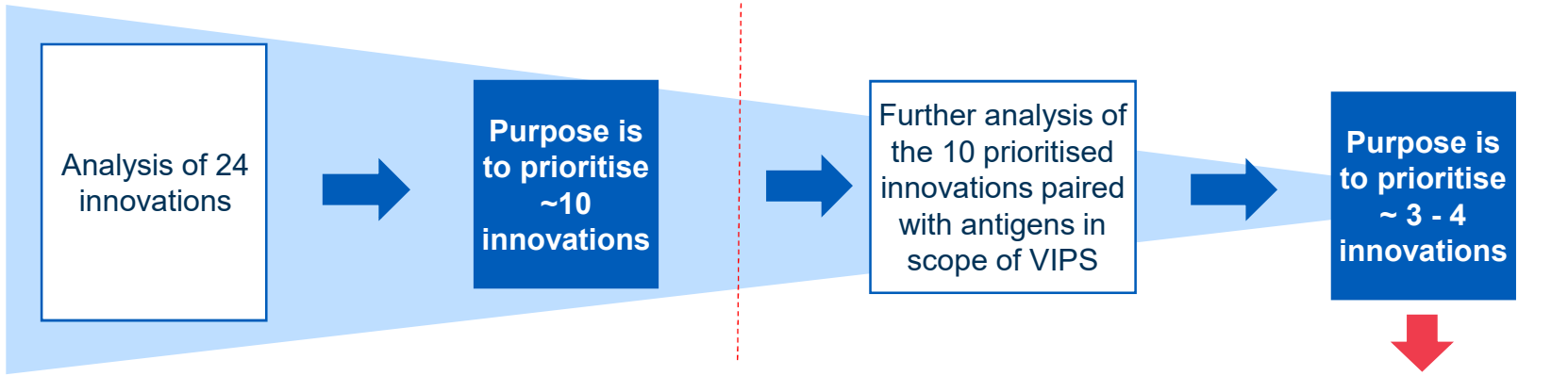
  - Provide feedback on 10 VIPS prioritized innovations from the perspective of technical feasibility, manufacturability, regulatory hurdles, alignment with manufacturer priorities, and incentives needed to encourage product development and uptake.

VIPS deliverables early 2020

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

Phase I:
The initial prioritisation of innovations

Phase II:
The final prioritisation of innovations paired with antigens



A report will be published, with the aim to send signals to innovation developers and vaccine manufacturers and partners on most valuable innovations, rationales and recommendations for next steps, and inform the research agenda
(both Phase I and II outcomes will be communicated at the same time)

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The Alliance is committed around a long-term vision for VIPS

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

Beyond prioritisation, the Alliance recognises the need to support product development and country uptake

Beyond 2019

As a next step, the Alliance will also consider how to **support the prioritised innovations beyond prioritisation and signalling**

Depending on each innovation, support may be needed for:

- **Product development**
- **Regulatory pathway**
- **Field studies**
- **Procurement**
- **Country uptake**
- **Etc.**

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