



Plenary 5 Evidence for Decision-Making

Global Vaccine and Immunization
Research Forum

20-22 March 2018; Bangkok, Thailand

Evidence for Decision-Making *Session objectives*

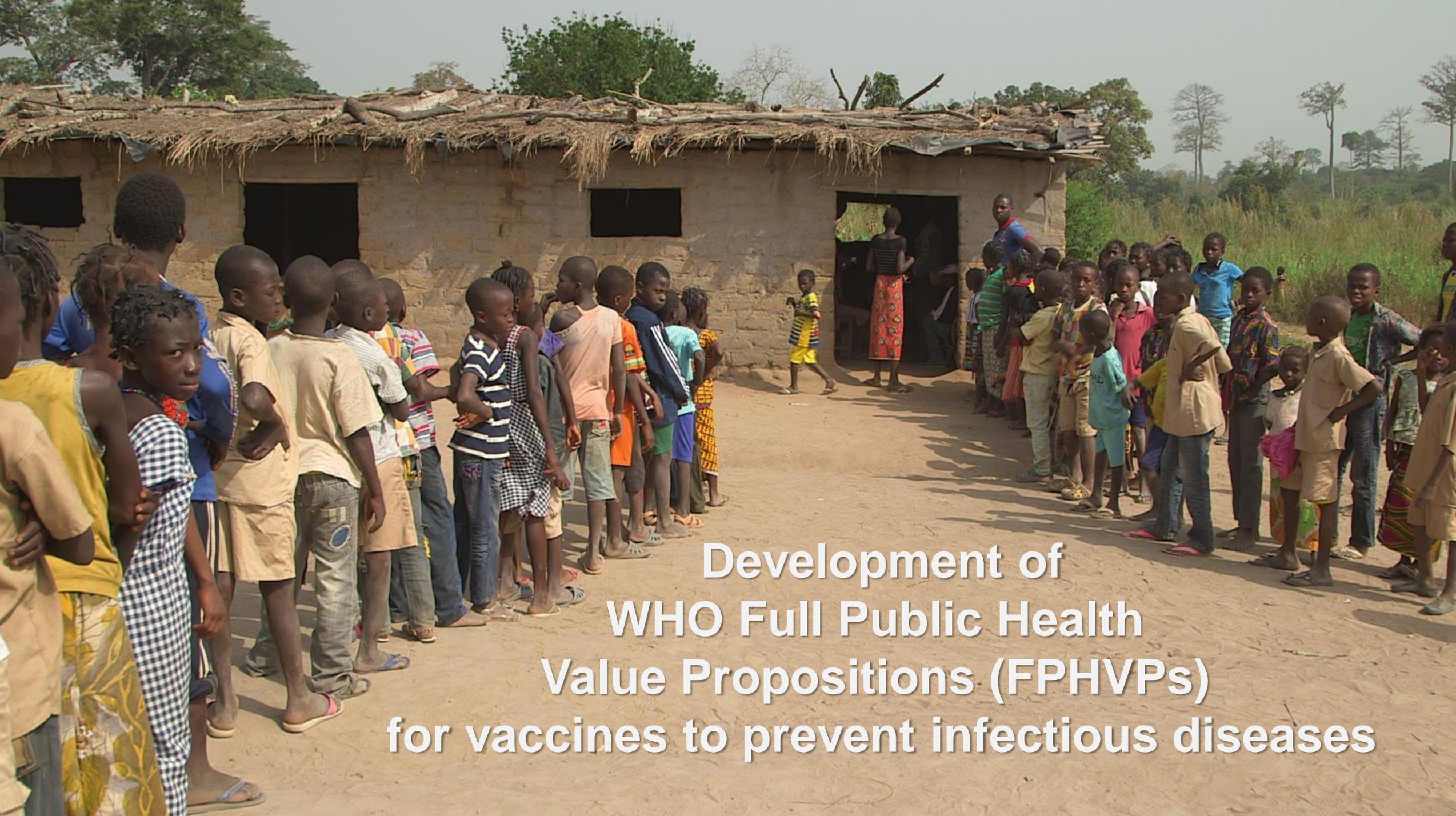
Foster a *common understanding* of what is meant by the term '*Full Public Health Value Proposition*'

Discuss the *benefits and utility of describing vaccine value propositions* in this broader sense; will the FPHVP perspective influence upstream and/or downstream decision-making?

Facilitate an *interactive discussion* with panelists and receive feedback from session participants on FPHVPs

Evidence for Decision-Making *Session agenda*

Topic	Time	Speaker / <i>Facilitator</i>
Introduction and background on WHO Full Public Health Value Proposition (PDVAC and IVIRAC)	15 min	David Kaslow
Views on the value proposition of new pipeline vaccines from different perspectives <ul style="list-style-type: none">○ MIC country representative○ Donors' perspective○ DCVMN's perspective○ IFPMA's perspective	30 min	<i>Rob Breiman</i> Cherry Kang Yot Teerawattananon Anita Zaidi Suresh Jadhav Jean-Antoine Zinsou
Facilitated and interactive discussion with panelists and session audience	45 min	<i>Rob Breiman</i>



**Development of
WHO Full Public Health
Value Propositions (FPHVPs)
for vaccines to prevent infectious diseases**

WHO's IVR develops guidance to accelerate development, licensure, and uptake of vaccine in Low- and Middle-Income Countries (LMICs)



Research &
Development



Licensure



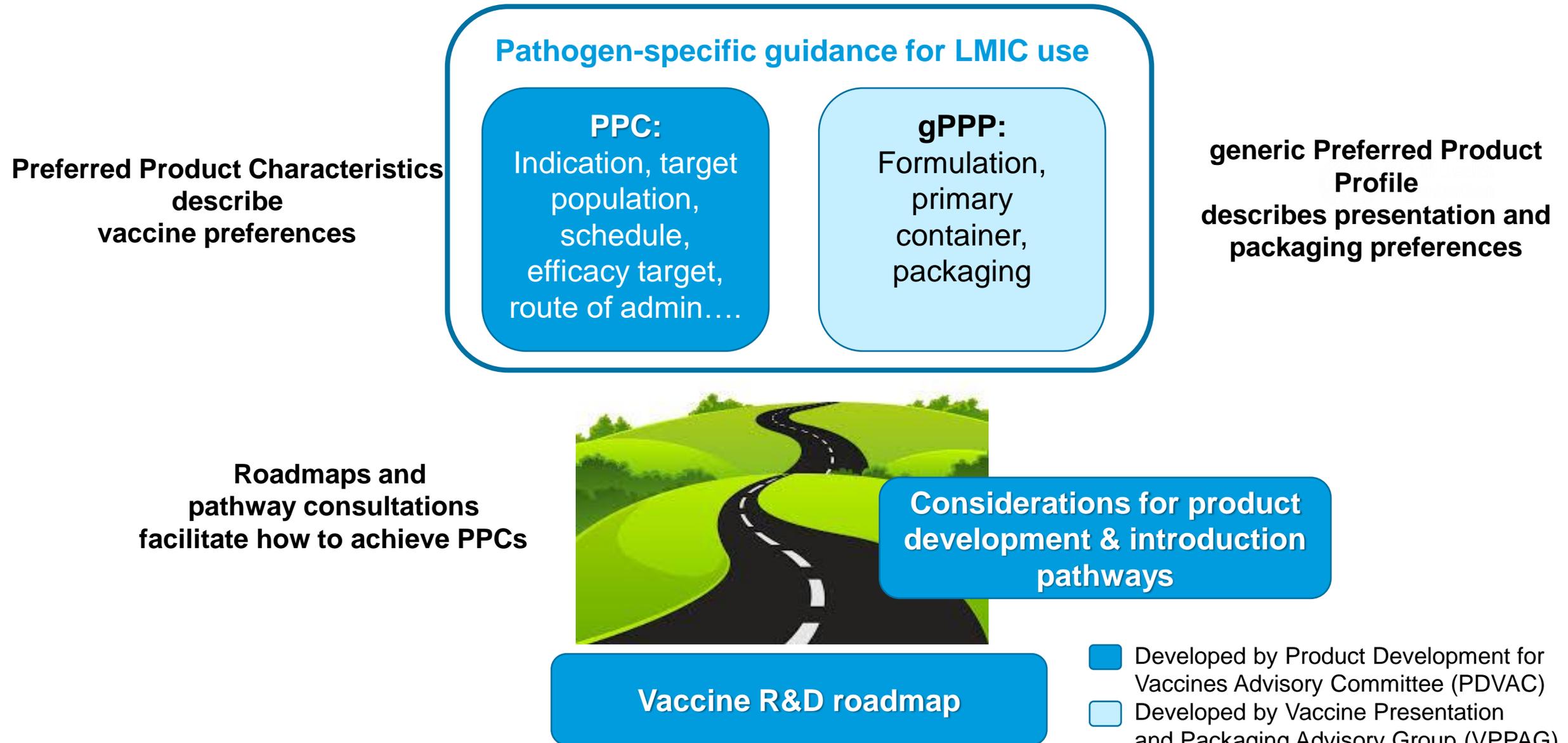
Uptake

Needs and preferences for LMICs countries must be ***clearly articulated*** and included ***early*** in vaccine product development and implementation strategies, to support an eventual ***policy recommendation***



Mind the gap: jumping from vaccine licensure to routine use *The Lancet* **387**: 1887 – 1889, 2016

Inter-relationship of WHO vaccine development guidance from early development to licensure



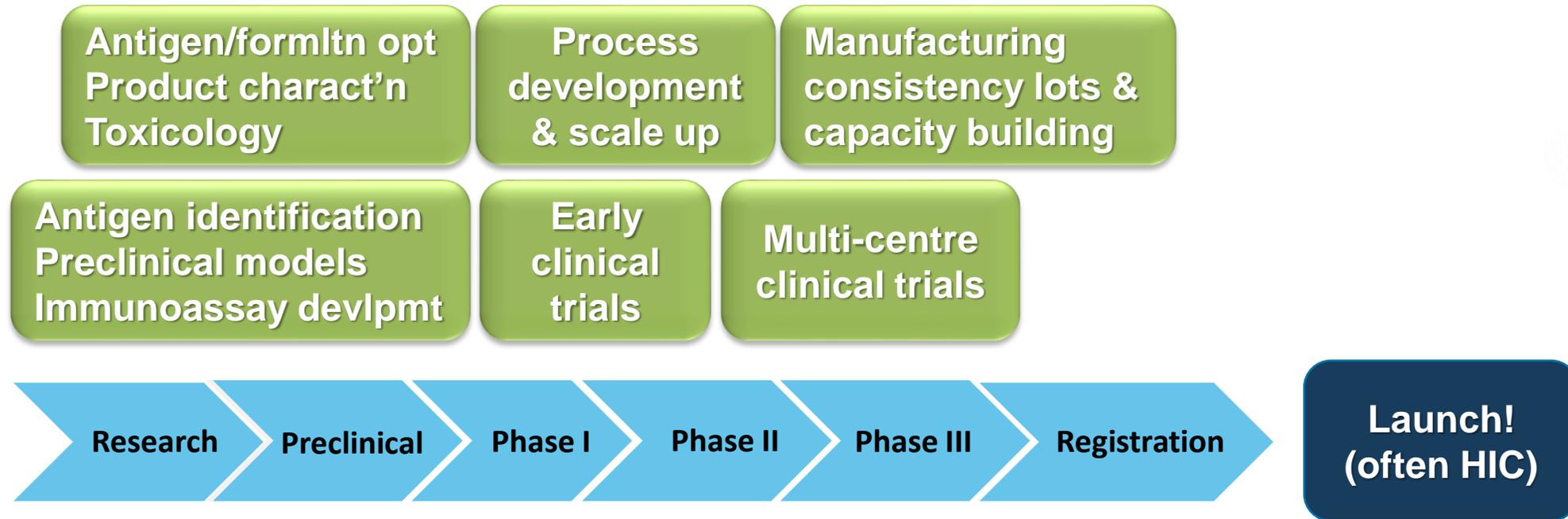
WHO PPCs seek to broaden the scope of Target Product Profiles (TPPs)* to incorporate LMIC needs



Parameter	WHO PPC	TPP
Focus	Pathogen-specific	Candidate (product) specific
Content	Describes preferences for LMICs	Sets minimal criteria for development
Audience	Any entity seeking eventual PQ/LMIC market	Stakeholders interested in return on investment
Purpose	Encourage innovation, broaden vaccine target populations	Guide investment decision-making
Criteria defined	Describes only preferences	Describes minimal and ideal ranges
Process of development	Public health stakeholder consultation	Within institutions

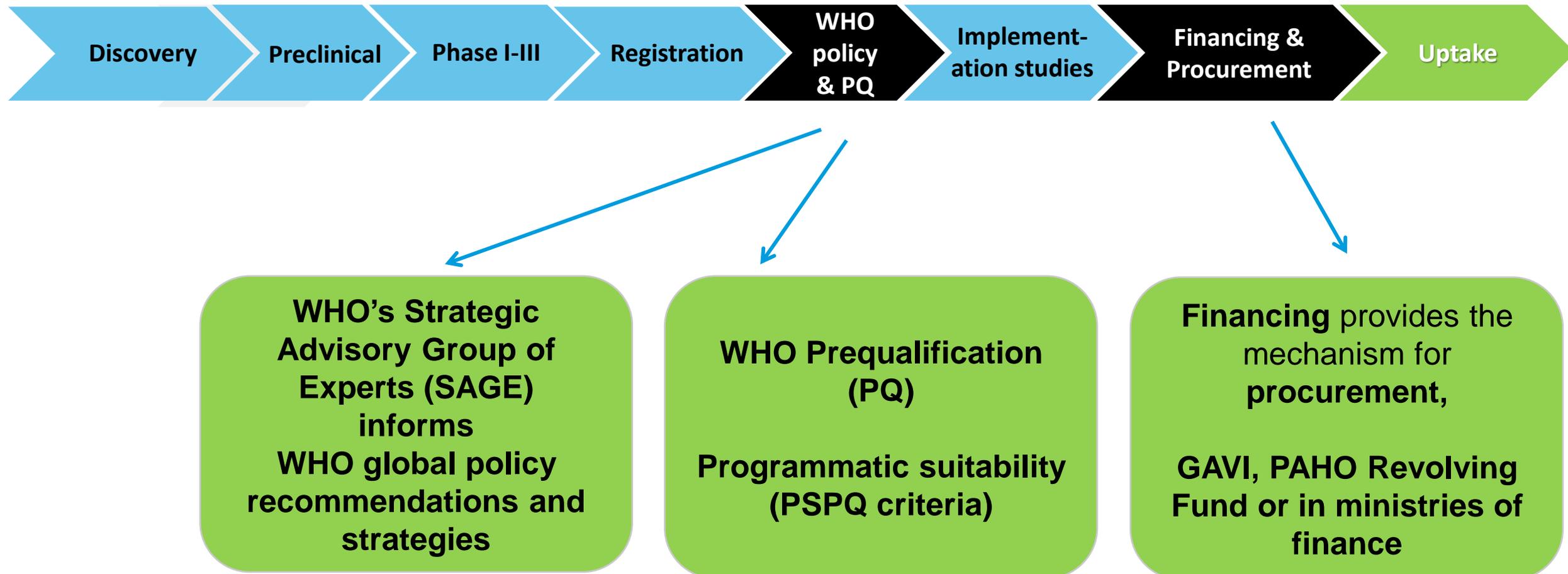
* TPPs are often product-specific and developed by other stakeholders and entities, typically private industry

Product development investments to licensure



How do we incentivize product development to meet LMIC policy and PQ requirements?

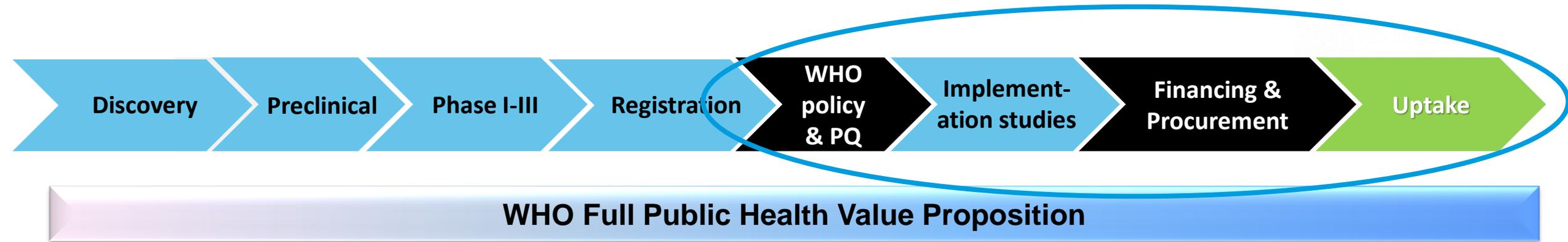
Additional steps for vaccine uptake in LMICs



The FPHVP for vaccines describes the global value of a vaccine

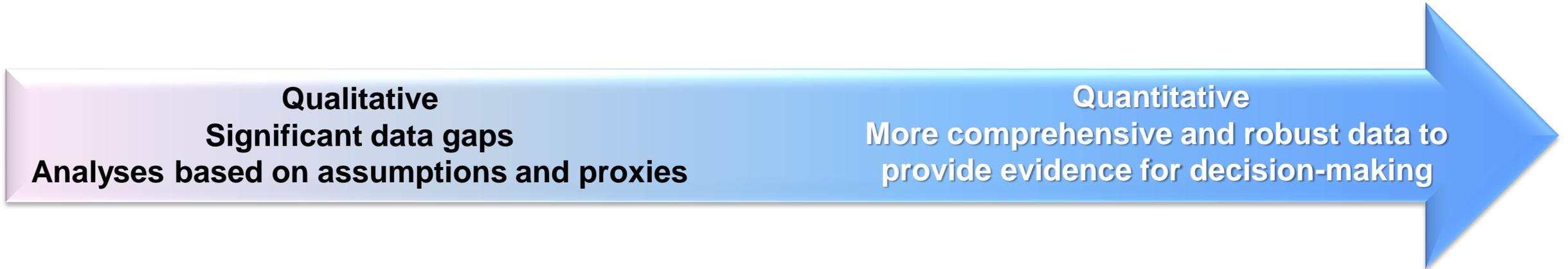
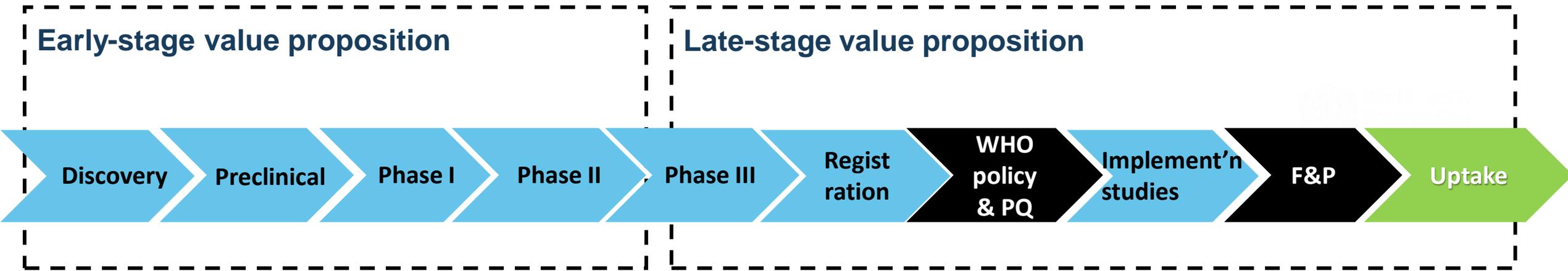


...and considers the data needed to support policy recommendations & uptake

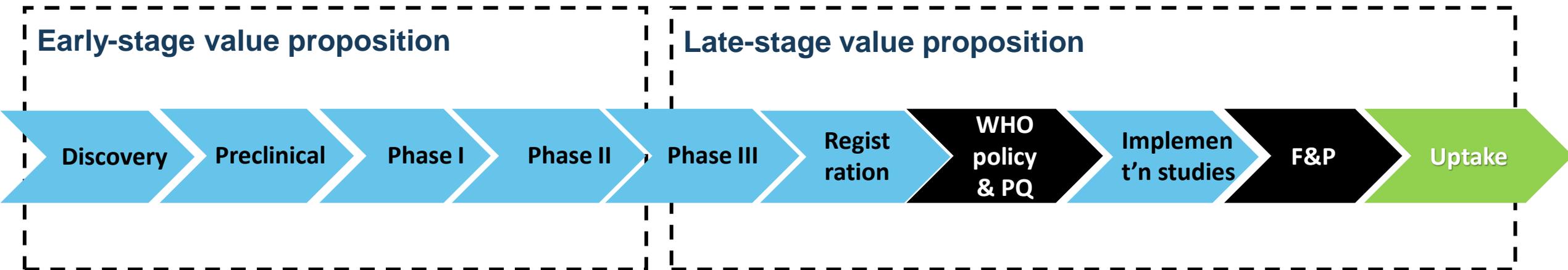


- Articulates the value of the vaccine **from the perspective of multiple stakeholders**
- End-to-end compendium of available evidence to support advocacy and inform decision making at various stages of product development
- Identifies gaps to guide funding decisions and assessment of risk

The availability of data to describe the FPHVP varies by development stage



The purpose of the FPHVP



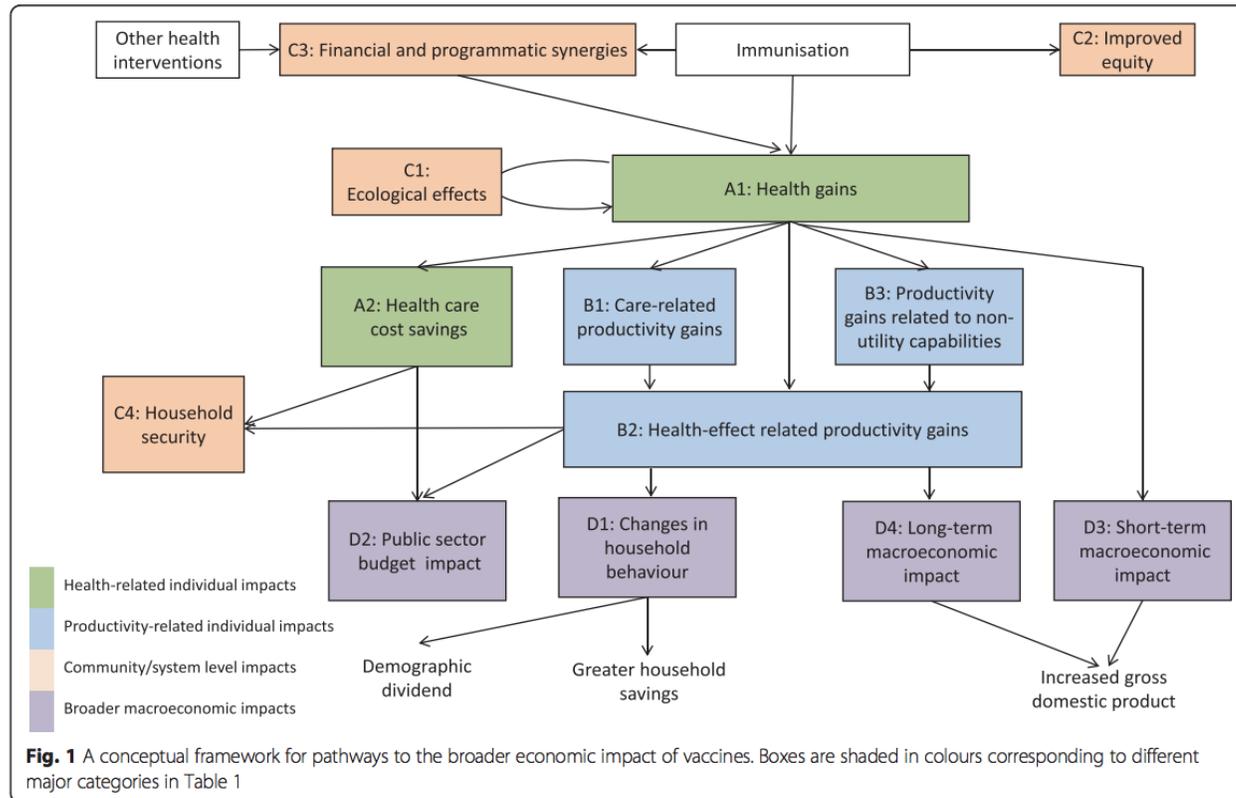
Goal of early stage VP:

- improve epidemiology/burden estimates
- evaluate the technical and commercial feasibility
- prime the vaccine pipeline

Goal of late stage VP:

- evaluate the full market potential of vaccine, **considering individual- and population-based benefit**
- inform return on investment/business case
- articulate evidence to support recommendation & uptake

Value of vaccines and immunization programs



Source: Jit et al. 2015

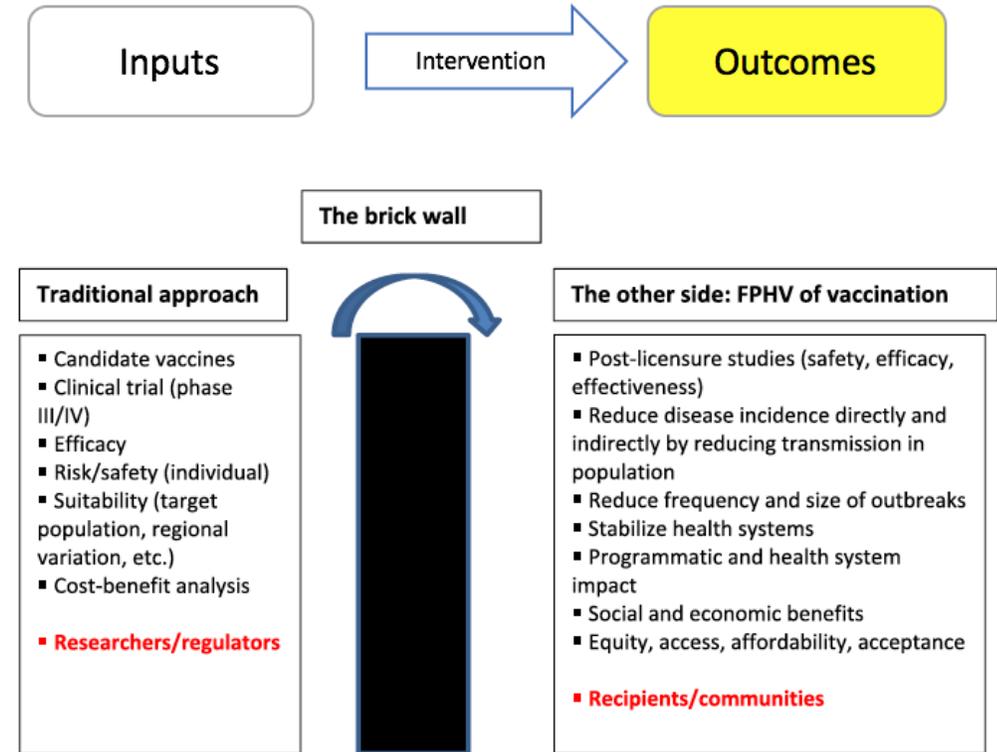


Fig. 2. The brick wall: Moving from vaccines to vaccination.

Source: Gessner et al. 2017

Traditional v FPHVP approach

Traditional approach based on:

- Efficacy (individual direct benefit) & effectiveness (direct and indirect health benefits)
- Risk/safety profile (individual)
- Cost-benefit analysis



FPHVP approach also based on:

- Disease reduction directly and indirectly by reducing:
 - Vaccine preventable disease incidence
 - All cause mortality
 - Under 5 mortality
 - Long-term sequelae
 - Pathogen transmission
 - Anti-microbial resistance
- Reducing frequency and size of outbreaks
- Stabilizing health systems
- Social and economic benefits
- Equity, access, affordability, acceptance and sustainability
- Protecting against financial risk

**Traditional
Benefit/Risk**

v

Full Public Health

Value Propositions

	Health		Non-health (Societal/Economic)	
	Direct	Indirect	Direct	Indirect
Individual				
Population				

1996: Ministers of Health and Interior from 16 African countries recognized epidemic meningitis as a high priority

2001: Creation of MVP (partnership between PATH and WHO) with a grant from the Bill & Melinda Gates Foundation

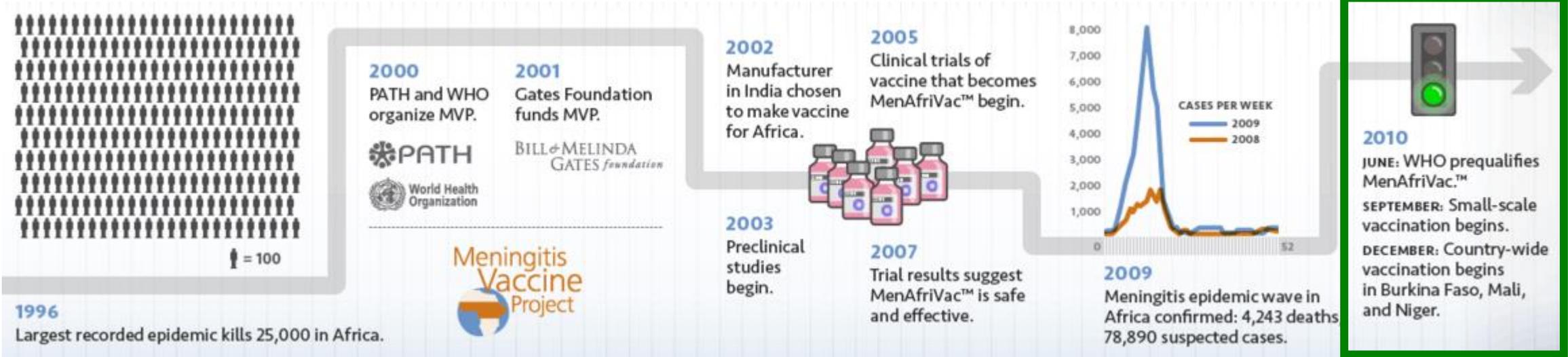
2001–2002: African public health officials emphasize the key importance of a low vaccine price for a sustainable supply

**Affordability is key to ensure sustainability,
< \$US 0.50/dose**

Case study: MenAfriVac development by the Meningitis Vaccine Project (MVP)



MenAfriVac development / introduction pathway



In collaboration with health authorities of 26 countries in sub-Saharan Africa and of India



>300MM doses delivered

2015/16: WHO PDVAC identified development of GBS vaccines suitable for maternal immunization (MI) in pregnancy and use in LMICs as public health priority

2016: WHO developed a PPC

2017: BMGF funded the WHO/LSHTM GBS value proposition project

Case study: Group B Streptococcus vaccine



Project goal to define the value of GBS vaccine by:

- Assessing the preventable burden of disease,
- Estimating expected costs/gains from vaccinating pregnant women

In order to:

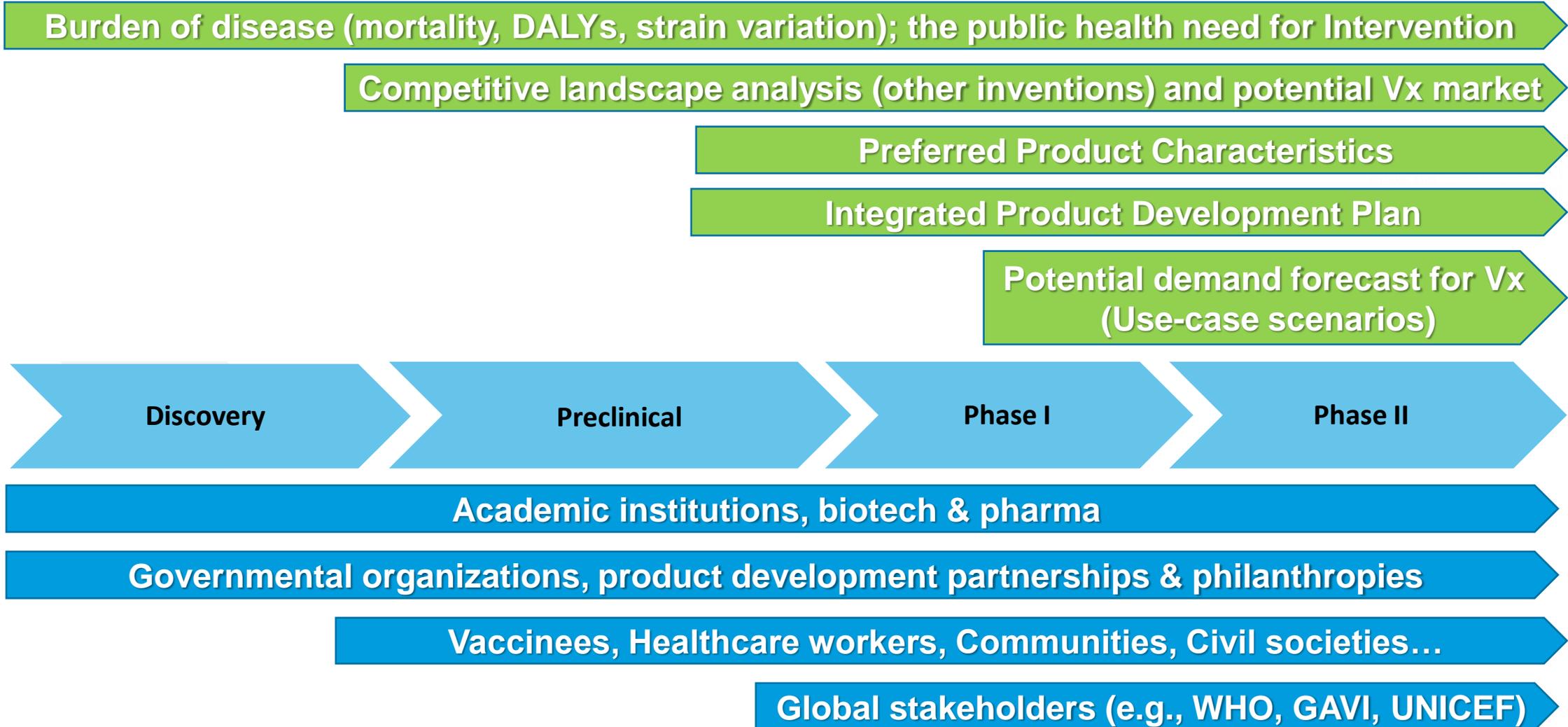
- Inform investments in product development and implementation research in readiness for Maternal Immunization vaccination platform
- Identify major data gaps as they relate to the creation of a favourable environment for future vaccine introduction in low resource countries

Preparation for policy recommendation and uptake for a vaccine EARLY in product development!

Case study: Group B Streptococcus vaccine



Early-stage value proposition focuses on vaccines up to clinical proof-of-concept



Late-stage value proposition focuses on vaccines post clinical proof-of-concept



Components of early stage Vx VP (accuracy refined, robustness improved)

Market assessment, strategic demand forecast and market shaping; return on investment

Vaccine impact on burden of disease and transmission (individual & population/societal effects)

Economic analysis of the value of the vaccine



Vaccinees, Healthcare workers, Communities, Civil societies...

Governmental organizations, product development partnerships & philanthropies

Global stakeholders (e.g., WHO, GAVI, UNICEF)

Country MoH & MoF

WHO oversight and guidance of vaccine product development and introduction



Availability of WHO public health value proposition data and robustness



PDVAC: Early stage (up to Phase II POC)

IVIR-AC: Policy preparation & decision-making

IPAC

PQ

SAGE

PDVAC: Product Development for Vaccines Advisory Committee

IVIR-AC: Immunization and Vaccines-related Implementation Research Advisory Committee

IPAC: Immunization Practices Advisory Committee

SAGE: Strategic Advisory Group of Experts on Immunization

PSPQ: Prequalification

Create alignment across a range of stakeholders, with respect to public health priorities

Provide a resource to effectively advocate for development of vaccines

Inform investment decisions at all stages of development

To accelerate suitability for and accessibility of vaccines to LMICs

The purpose of WHO
Full Public Health
Value Proposition
(FPHVP)

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Back up slides

Content of the WHO FPHVP

Including, but not limited to:

- Strategic priority vaccines and the summary of WHO PPCs
- Global public health need for the vaccine
- Stakeholder analysis and involvement
- Development of the vaccine
- Assessment of the vaccine development pipeline
- Defining the market for the vaccine and the need for shaping
- Estimation of disease burden and transmission
- Impact of the vaccine on burden of disease and transmission
- Economic analysis of the value of the vaccine
- Financing of the vaccine

Questions for the panel

- Need a question about definitions? Alignment on terminology?
- - what information/evidence “end users“ at country level should provide to/ consider important for developers of new products/technologies, in order for them to have a better understanding of LMIC needs, and a broader PHVP
- - visa versa: for the public health value proposition of early development of products/technologies how early should developers/manufacturers start to consider the economic aspects of LMIC markets, what economic/vaccine impact studies are needed and at what stage of development? For example investment case for GBS where cost effectiveness and implementation modelling is taking place for a candidate in early clinical development
- - what economic studies should be included as part of the PHVP to demonstrate the Value for Money of early and late stage products.
- - what is the role of the donor e.g. BMGF and GAVI (market shaping) across the whole pathway?
- Is the concept of articulating the FPHVP likely to facilitate the development of global vaccine products, and accelerate the availability and access of products to LMICs?
- What are the priority components to define in early vs late stage product development?