



Workshop 7 New Vaccine Pipeline Lessons Learned and Accelerating Progress

GLOBAL VACCINE PIPELINE AND VALUE PROPOSITION

Global Vaccine and Immunization
Research Forum

20-22 March 2018; Bangkok, Thailand

Global Vaccine Pipeline and Value Proposition

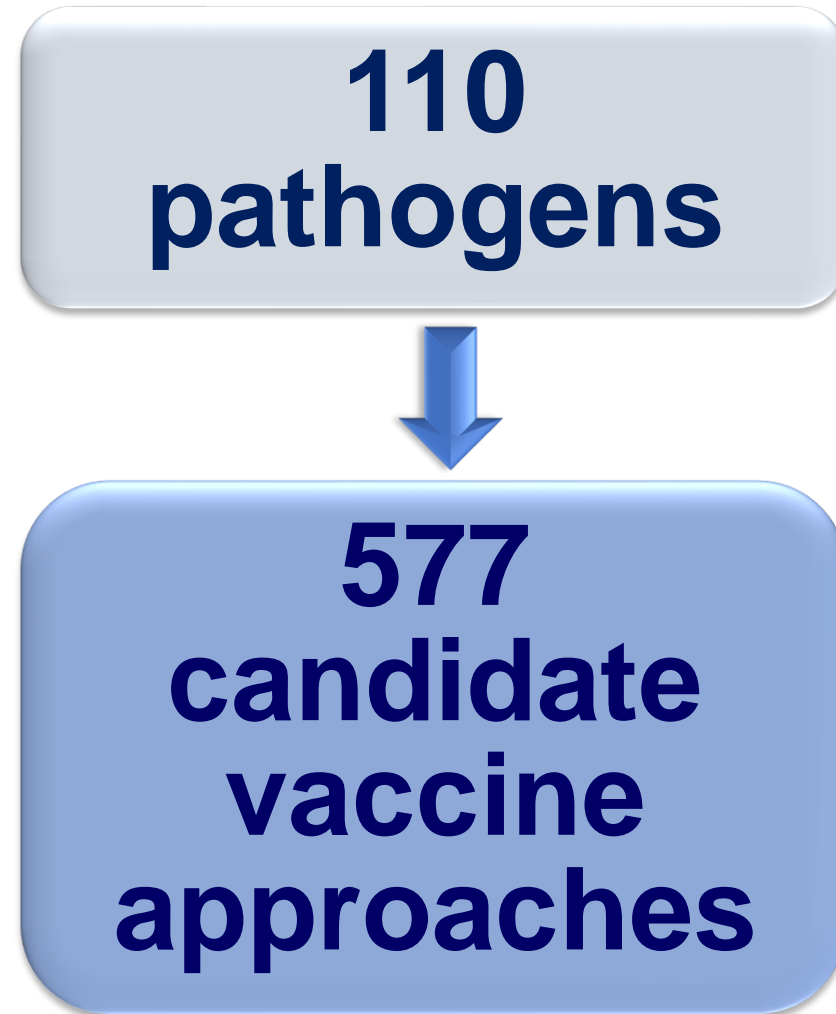
Presentation and panel discussion objectives

Review progress toward licensure and launch of vaccines against (currently) non-vaccine-preventable diseases

Further discuss the concept of *full public health value proposition* (FPHVP)

Examples of FPHVP in *guiding investment decisions* in vaccine research and development

Progress toward licensure and launch of vaccines against (currently) non-vaccine-preventable diseases



Reference:

Jordan Report 2012 APPENDIX A: Status of Vaccine Research and Development
<https://www.niaid.nih.gov/sites/default/files/jr2012appendixes.pdf>

Progress toward licensure and launch of vaccines against (currently) non-vaccine-preventable diseases

Early stage pipeline

WHO Product Development for Vaccines Advisory Committee Pipeline Analyses 2014-2017



32 pathogens

| | | | |
|--------|--------------------------------|-----------|------------------------------|
| Viral | • Cytomegalovirus | Gram - | • Campylobacter jejuni |
| | • Chikungunya virus | | • Chlamydia trachomatis |
| | • Dengue virus | | • Enterotoxigenic E. Coli |
| | • Ebola/Marburg virus | | • Helicobacter pylori |
| | • Enterovirus 71 | | • Neisseria gonorrhoea |
| | • Human Immunodeficiency virus | | • Non-typhoidal salmonella |
| | • Herpes Simplex virus | | • Salmonella paratyphoid |
| | • Influenza (Universal) | | • Shigella ssp |
| | • Respiratory Syncytial Virus | | • Vibrio cholerae |
| | • MERS-CoA virus | | |
| | • Nipah virus | | • Mycobacterium tuberculosis |
| | • Norovirus | | |
| | • Zika virus | | |
| Gram + | • Clostridium difficile | Parasitic | • Chagas disease |
| | • Group A Streptococcus | | • Hookworm |
| | • Group B Streptococcus | | • Leishmaniasis |
| | • Staphylococcus aureus | | • Malaria |
| | • Streptococcus pneumoniae | | • Schistosomiasis |

Reference:

WHO Product Development for Vaccines Advisory Committee

<http://www.who.int/immunization/research/committees/pdvac/en/>

Progress toward licensure and launch of vaccines against (currently) non-vaccine-preventable diseases

Pipeline trackers

Tracking the New Vaccine Pipeline

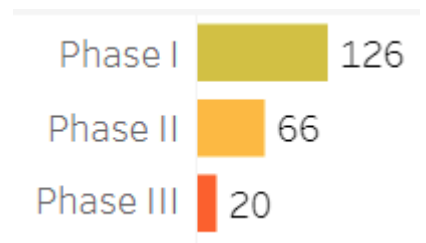
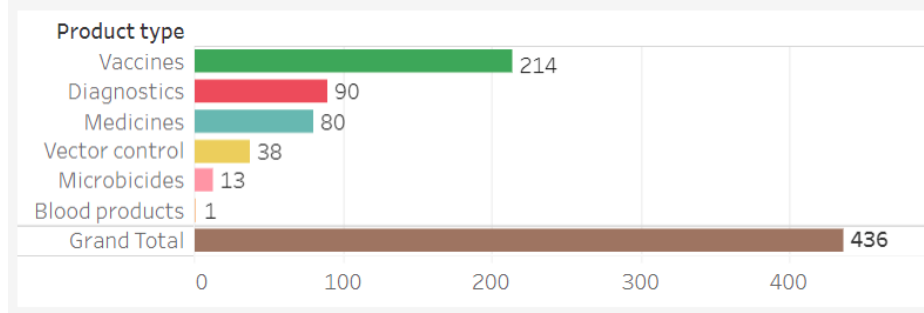
WHO vaccine pipeline tracker

| Pathogen | Month of most recent update | Updating Partner |
|-------------------------|-----------------------------|--------------------------|
| HIV | June 2017 | HVTN, IAVI, MHRP |
| Malaria | November 2017 | University of Washington |
| TB | November 2017 | Aeras |
| Dengue | November 2017 | WHO Secretariat |
| RSV | November 2017 | PATH |
| Rotavirus | November 2017 | PATH |
| Other enterics | November 2017 | PATH |
| Zika | January 2018 | WHO Secretariat |
| Lassa, MERS-CoV, Nipah | November 2017 | CEPI |
| Ebola/Marburg | November 2017 | Oxford |
| Pneumococcal infections | November 2017 | MSF Epicentre |

http://www.who.int/immunization/research/vaccine_pipeline_tracker_spreadsheet/en/

Global Observatory on Health R&D

Number of candidate products by type



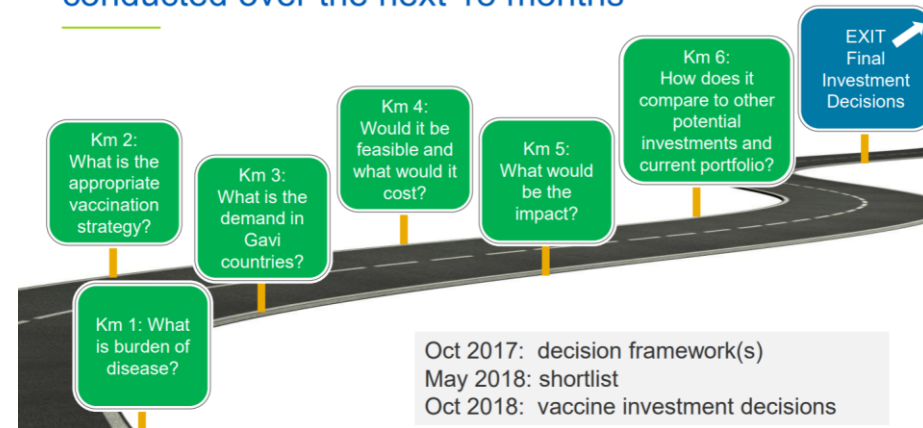
http://www.who.int/research-observatory/monitoring/processes/health_products/en/

Progress toward licensure and launch of vaccines against (currently) non-vaccine-preventable diseases

Later stage pipeline

GAVI, the Vaccine Alliance Vaccine Investment Strategy #3 (2019)

A robust and evidence-based process will be conducted over the next 18 months



Preliminary list to be further reviewed:

Dengue
Hepatitis A
Hepatitis E
Influenza seasonal, maternal (pandemic?)
Malaria (refresh with no decision in 2018)
Mening CYWX
Mumps/MMR
Rabies, Rabies Ig/mAb
Typhoid
RSV (& RSV mAb?)
Group B strep
OCV
Diphtheria (booster, maternal)
Diphtheria antitoxin

Hep B birth dose
Pertussis (booster)
PCV catchup
IPV
Tetanus toxoid (booster, maternal)
Ebola (pre-emptive vaccination)
Zika

Norovirus
ETEC
HIV
TB 2nd generation
Chikungunya
CEPI vaccines?



Vaccines that might be licensed by 2023

- CEPI vaccines
- Chikungunya
- Ebola
- ETEC
- Group B Strep
- HIV
- Mening ACYWXX
- Norovirus
- RSV
- TB 2nd Gen
- Zika

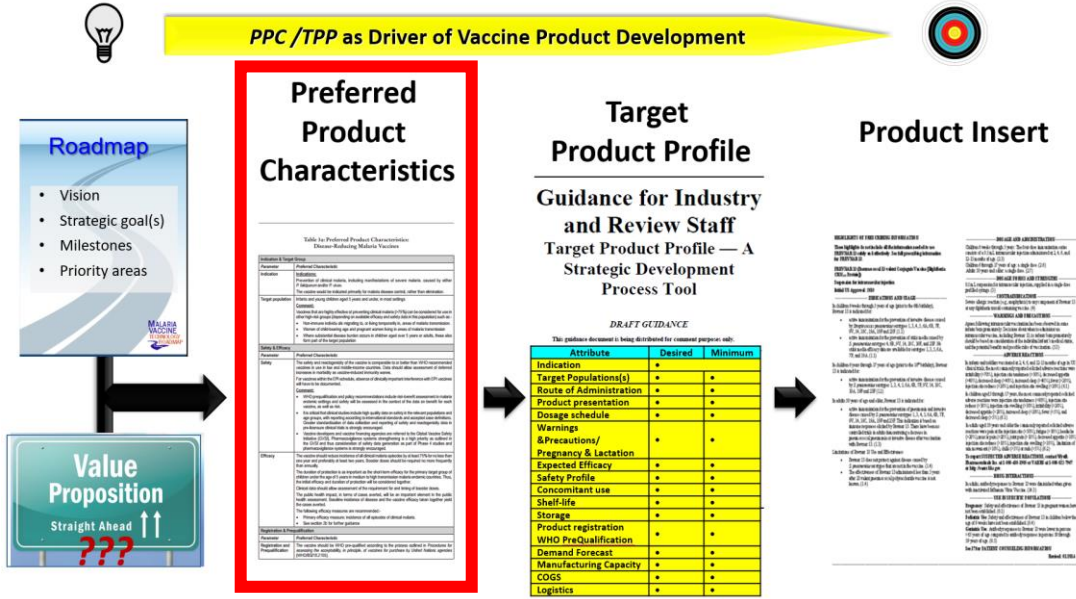


Reference:

WHO Product Development for Vaccines Advisory Committee

<http://www.who.int/immunization/research/committees/pdvac/en/>

Global Vaccine and Immunization Research Forum Hilton Sandton Hotel, Johannesburg, South Africa, 15-17 March 2016



The concept of full public health value proposition (FPHVP)

If we build it, will anyone want to use it???

Value Proposition
Straight Ahead ↑↑



Mind the gap: jumping from vaccine licensure to routine use

The first valley of death



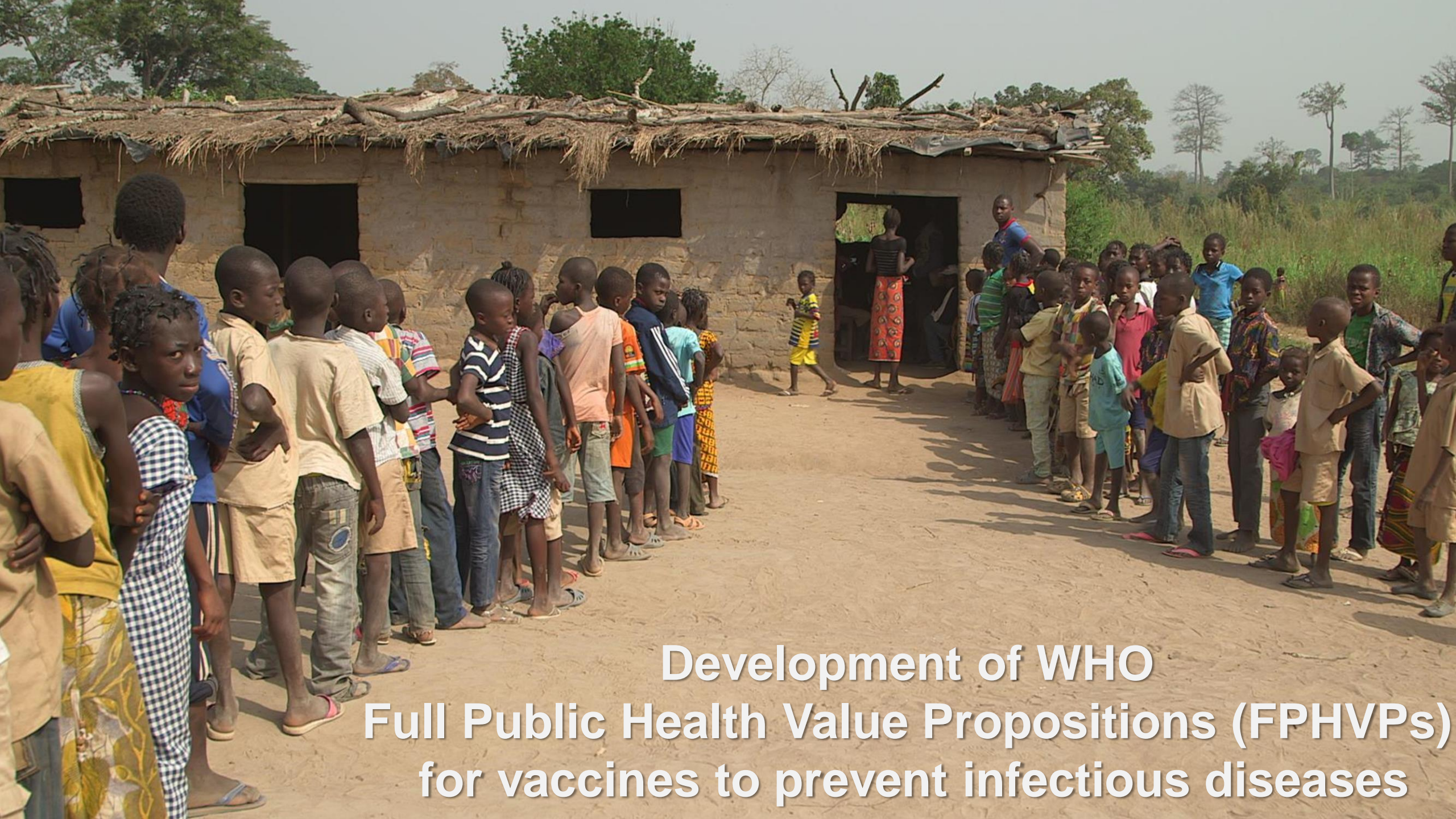
<http://www.nature.com/news/2008/080611/full/453840a.html>

A second valley of death?



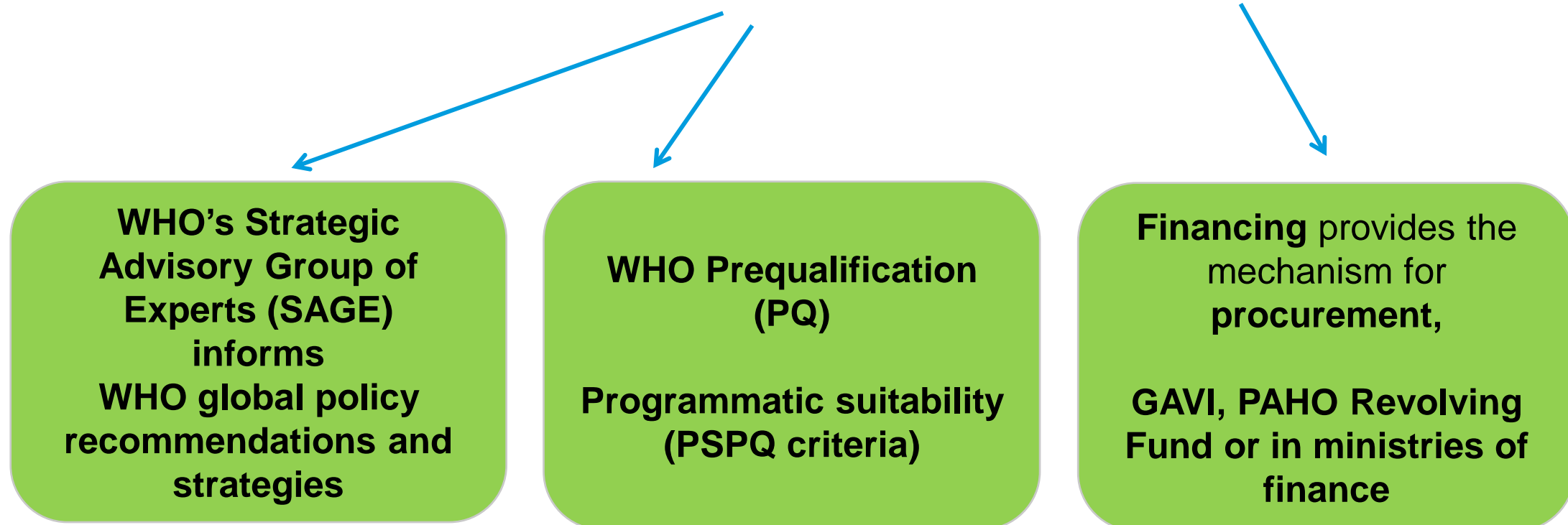
www.lancet.com Vol 387 May 7, 2016

“Mind the gaps”:
Two “valleys of death”?



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

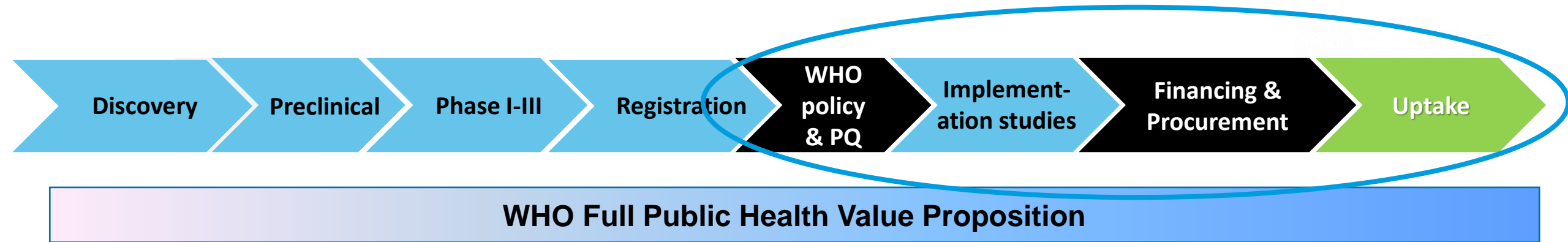
Additional steps for vaccine uptake in LMICs



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

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

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

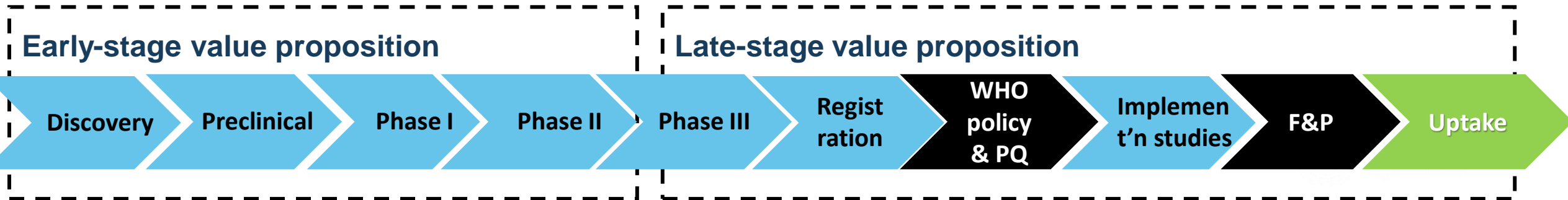
**Traditional Risk/
Benefit**

v

Full Public Health

**Value
Propositions**

The goals of the FPHVP and availability of data varies by development stage



Goal of early stage VP:

- improve epidemiology/burden estimates
- consider the landscape of other interventions
- evaluate the technical and commercial feasibility
- prime the vaccine pipeline with relevant candidates

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

Qualitative

Significant data gaps

Analyses based on assumptions and proxies

Quantitative

More comprehensive and robust data to provide evidence for decision-making

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)

Back-up slide

Content of the WHO FPHVP Early Stage

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

Sustainability

Goals

MDGs

Health



SDGs

Poverty & Equity

Value

PPC/TPP

*Health
Individual
Direct*



FPHVP

*Societal/Economic
Population
Direct & Indirect*

Sustainability

Pipeline/Supply

Traditional

*Clinical Developmt
Regulatory pathways
↓ Vaccine price /
↑ Quality std*



Reframe

*Molecular/Structural
Alternative licensure
Supply/Demand alignment*

Partnership

DoV

*GVAP
PPP/PDPs*



???