

# ACCELERATING VACCINE DELIVERY AND DEVELOPMENT

Evolving Vaccine Ecosystem Technologies and Partnerships

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David Robinson  
Bill & Melinda Gates Foundation

# WE SUPPORT VACCINE RESEARCH AND DEVELOPMENT IN PURSUIT OF OUR CORE GOAL

*All countries and individuals can access vaccines whenever needed*

*meet WHO prequalification standards (or equivalent)*

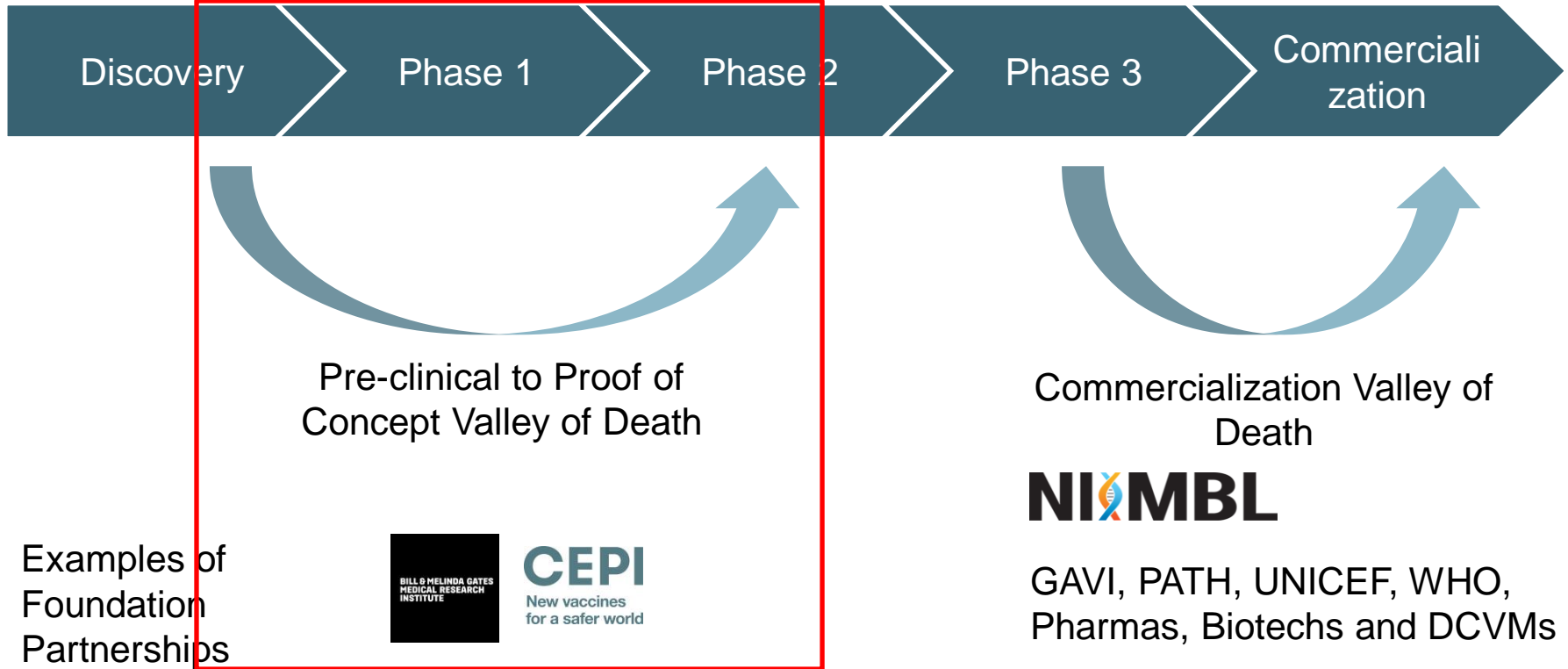
To ensure a **secure and sustainable supply of consistently high quality, appropriately priced vaccines** that meet the **demands of local markets**

*Within WHO definition of a "fully immunized child"*

*varied by market to account for ability to pay and need for financial incentive to spur development*

*Have the characteristics and packaging which enable maximum coverage by local healthcare workers*

# WE UTILIZE A PARTNER NETWORK TO ACCELERATE TECHNOLOGIES THROUGH TWO VALLEYS OF DEATH



# / GATES MEDICAL RESEARCH INSTITUTE

## MISSION

DEVELOP PRODUCTS TO ...



**ENTERIC AND  
DIARRHEAL DISEASES**



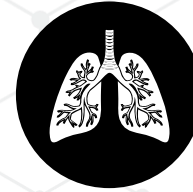
End diarrheal deaths  
in children



**MALARIA**



Eradicate malaria

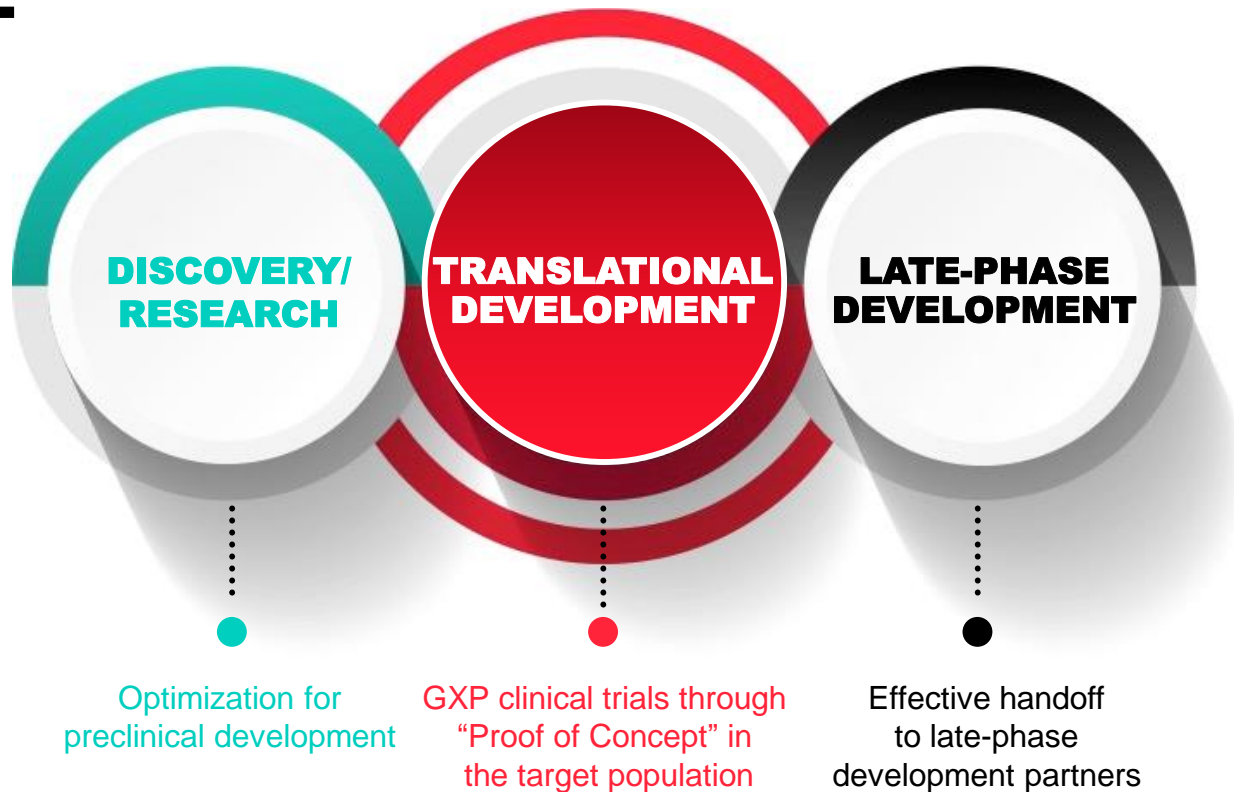


**TUBERCULOSIS**

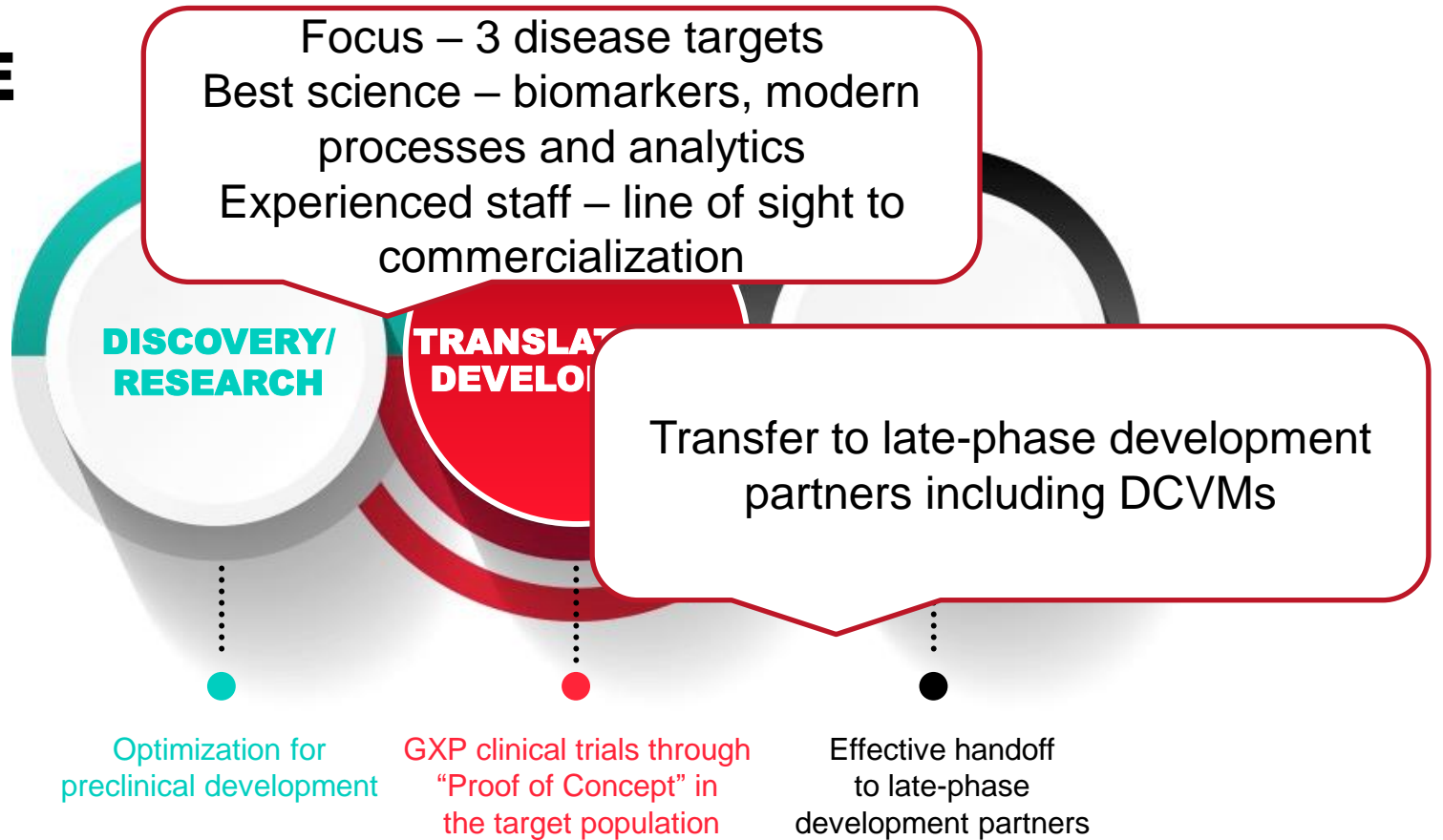


Accelerate the end  
of the tuberculosis epidemic

# / SCOPE



# / SCOPE



# COALITION FOR EPIDEMIC PREPAREDNESS INNOVATION (CEPI) VISION, MISSION, AND SCOPE



## Vision:

Vaccines can prevent outbreaks of emerging infectious diseases from becoming humanitarian crises.



## Mission:

To stimulate, finance and co-ordinate vaccine development against diseases with epidemic potential in cases where market incentives fail.



## Scope:

**CEPI takes a comprehensive approach to vaccine development, focusing on two initial priorities.**

1. CEPI will bring priority vaccine candidates through the end of phase II clinical trials.
2. CEPI will support vaccine platforms that can be rapidly deployed against known and unknown pathogens.

# COALITION FOR EPIDEMIC PREPAREDNESS INNOVATION (CEPI) VISION, MISSION, AND SCOPE

First call focused on proposals to develop vaccines through Phase II that targeted:  
MERS, Lassa and Nipah

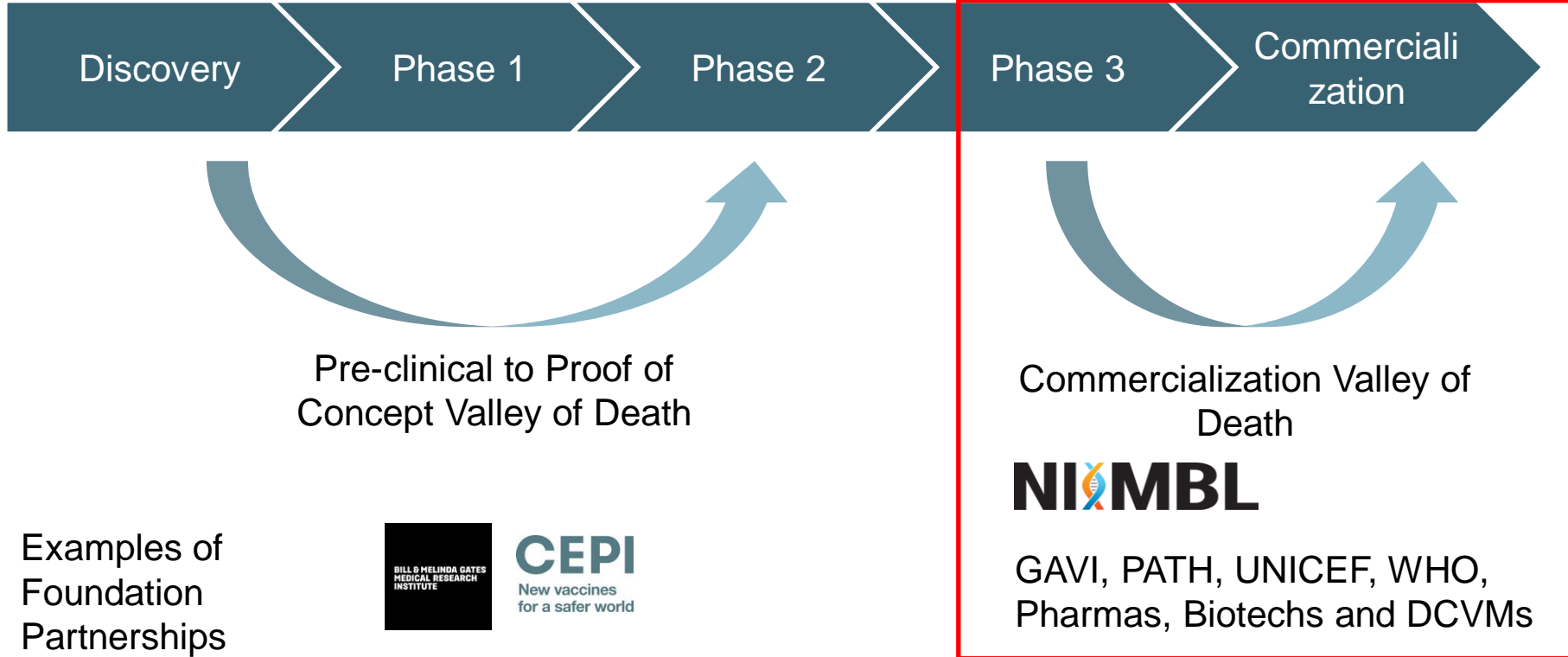
Patrick Florent  
leading Working  
Group on  
Sustainable  
Manufacturing

Second call focused on platform technologies targeting:  
16 weeks from antigen to product release for clinical studies  
6 weeks from first dose to clinical benefit  
8 weeks to make and release 100,000 doses

1. CEPI will bring priority vaccine candidates through the end of phase II clinical trials.
2. CEPI will support vaccine platforms that can be rapidly deployed against known and unknown pathogens.



# WE UTILIZE A PARTNER NETWORK TO ACCELERATE TECHNOLOGIES THROUGH TWO VALLEYS OF DEATH



Examples of  
Foundation  
Partnerships



**CEPI**  
New vaccines  
for a safer world

# THE FOUNDATION IS UNDER DISCUSSION WITH NIIMBL TO SET UP A COLLABORATION FOR GLOBAL HEALTH



## Our Mission

The NIIMBL mission is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness in this industry.

AMERICAN INNOVATION AT WORK **NIIMBL**

*The National Institute for Innovation in Manufacturing and Biopharmaceuticals was developed under the US National Institute of Standards and Technology*

## How we want to work together:

- Collaborate to de-risk technologies of mutual interest to global health and broader biopharmaceutical industry
- Introduce global health challenges to NIIMBL membership of academics, pharma and biotech
- Joint funding of priority programs through RFP call
- Partner on solutions for workforce development and regulatory engagement

# THE FOUNDATION IS UNDER DISCUSSION WITH NUMBL TO SET UP A COLLABORATION FOR GLOBAL HEALTH

Awarded over \$30 million in funding for projects such as virtual reality training, next generation sequencing for adventitious agent testing etc.

create and train a workforce in biopharmaceutical manufacturing

Ray Prasad (BMGF) will lead effort to identify projects

er:  
ologies of health and pharmaceutical industry

- Introduce global health challenges to

Proposing to create a Global Health Fund focused on advancing technology solutions that have a direct impact on manufacturing and releasing biologics and vaccines for global health

development and regulatory engagement

*The National Institute for Innovation in Manufacturing and Biopharmaceuticals was developed under the US National Institute of Standards and Technology*

# CASE STUDY: SUPPORTING UNIVERCELLS' NEVOLINE PLATFORM FOR MODULAR VACCINE MANUFACTURING

## Highly intensified, fully integrated modular manufacturing platforms

- > Reduction of process footprint
- > Simplified operations
- > High containment & safety allowing GAP III compliance
- > Drastic reduction of CAPEX
- > Rapid deployment of production capacity



Pre-clinical to Proof of Concept Valley of Death

Commercialization Valley of Death

Foundation funding Univercells through proof of concept

Univercells exploring partnerships to commercialize platform

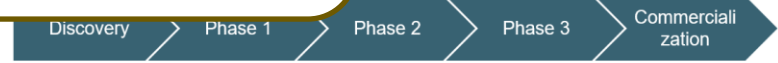
# CASE STUDY: S PLATFORM FOR

# NEVOLINE ACTURING

Low capital costs of new modular facilities lowers barrier to entry for regional and local manufacturing

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# TECHNOLOGIES ARE ONLY ONE ELEMENT OF ACCELERATING DEVELOPMENT: HOLISTIC UNDERSTANDING IS REQUIRED



## Central / Network-level considerations

- 1 Discovery and early clinical development
- 2 CMC and analytic process development



## Manufacturer considerations

- 1 **Materials** sourcing for supply chain
- 2 **Clinical development** (clinical trials, reg. submission)
- 3 **Tech transfer** and **process validation**
  - Bulk, formulation, and analytical



## Talent considerations

- 1 **Talent and capability building** at facility (engineering, QA/QC, line operation, process dev., medical/PV)
- 2 Vaccine-specific **workforce development**



## Infrastructure considerations

- 1 **Regulatory oversight**
  - NRA capability building
  - PV and PQC oversight
- 2 Local **infrastructure** (transport, utilities)
- 3 **Government** buy-in and support (including policy)
- 4 **Health sciences infrastructure and support** (technical service providers, plant design, air and water handling)
- 5 **Vaccine procurement systems**

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## Manufacturer considerations

1 Materials sourcing for supply

development (e.g.,

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rmulation, and

erations

capability building

, process dev., medical/P

Ensuring continued high quality is our number one priority!

Need to ensure a well trained workforce

## Central / Network considerations

1 Discovery and early clinical development

2 CMC and analytic process development

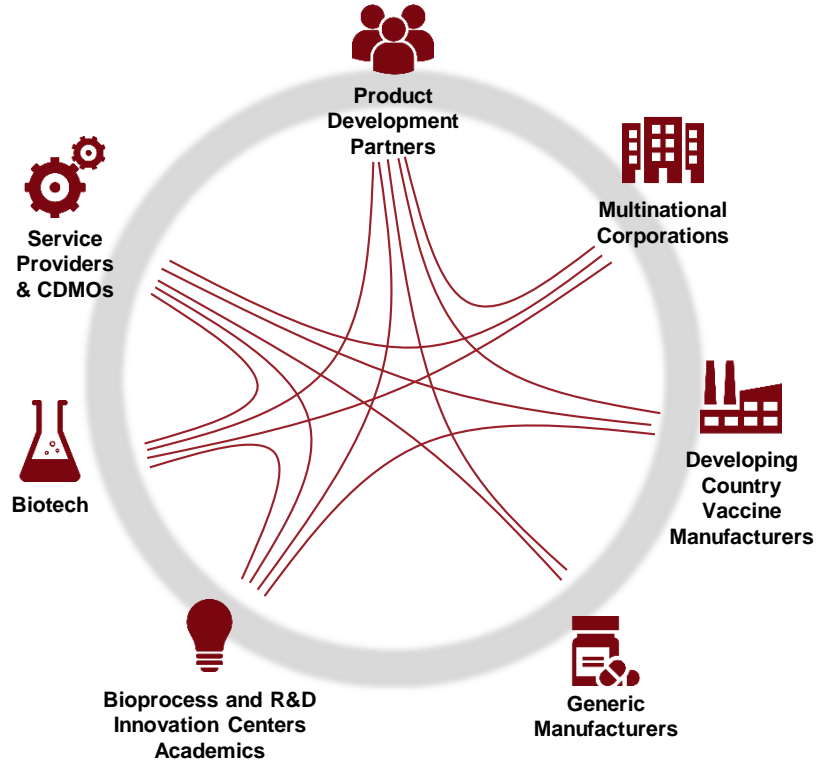
Need appropriately staffed and skilled National Regulatory Authorities

3 Government buy-in and support (including policy)

4 Health sciences infrastructure and support (technical service providers, plant design, air and water handling)

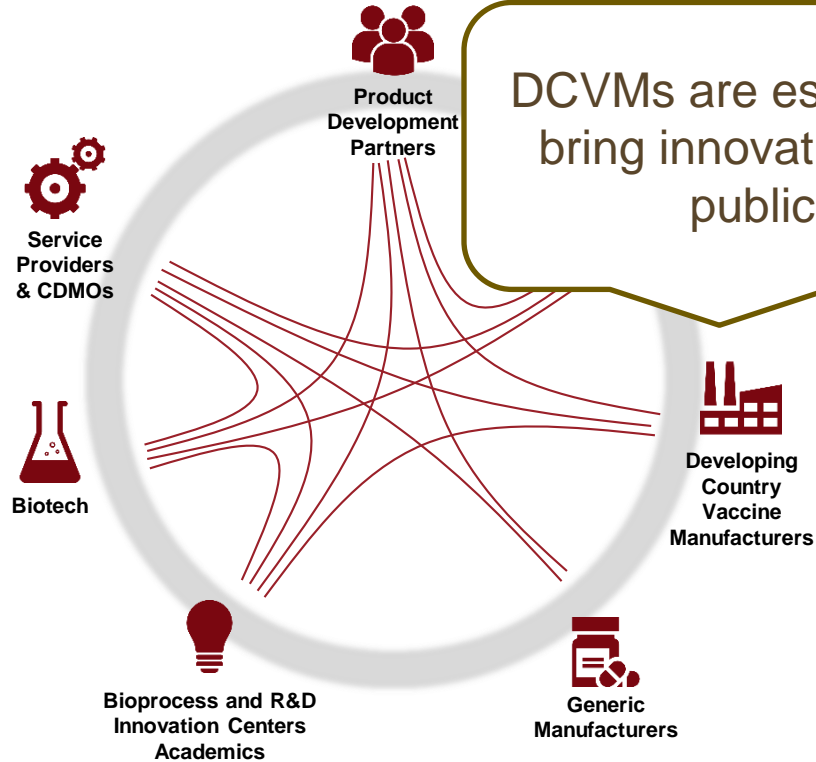
5 Vaccine procurement systems

# OUR ABILITY TO ACHIEVE IMPACT IS DEPENDENT UPON PARTNERSHIPS





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DCVMs are essential in order to help bring innovations to the market for public health impact

THANK YOU!

谢谢

Terima kasih

متشكراً

धन्यवाद

Cảm ơn bạn

Danke

Dank u

감사합니다

شكراً

ขอบคุณ

Gracias

Obrigado

Merci