

# 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)*

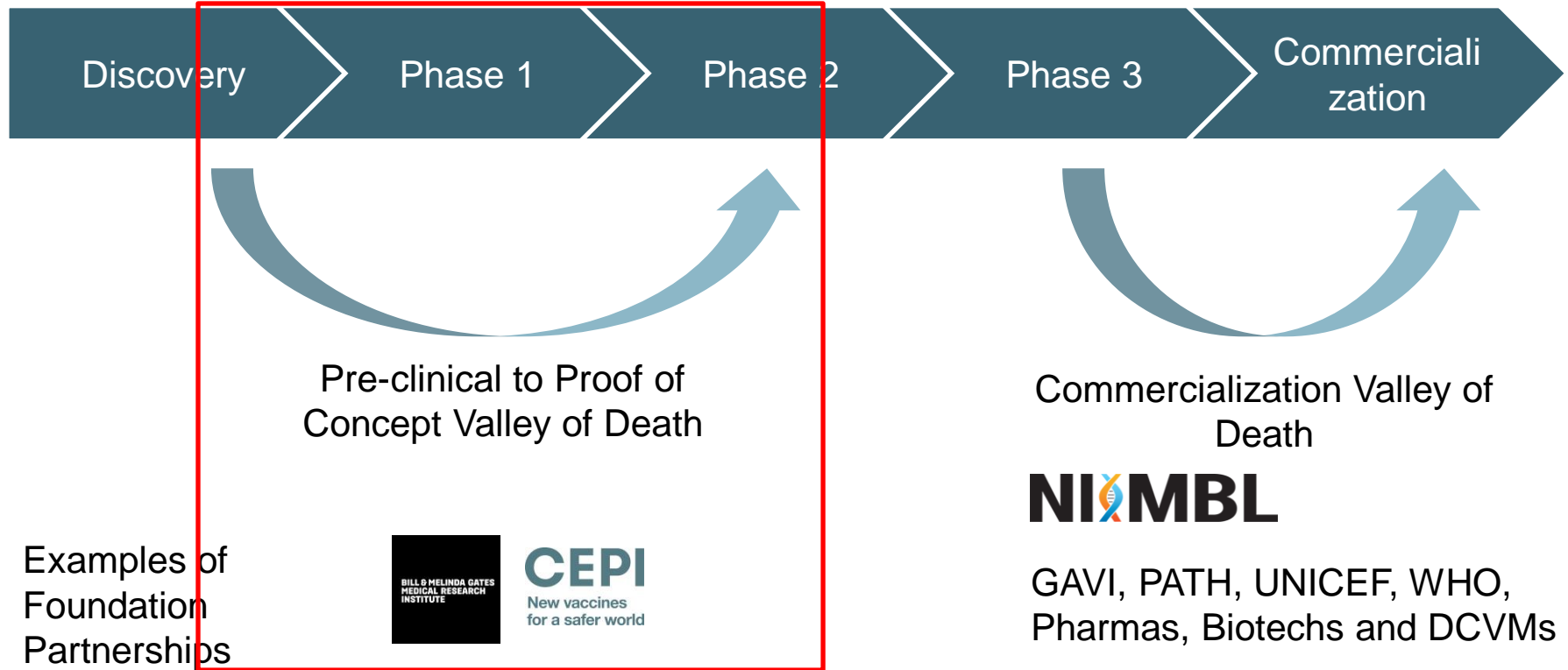
To ensure a secure and sustainable supply of consistently high quality,  
appropriately priced vaccines that meet the demands of local markets

*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

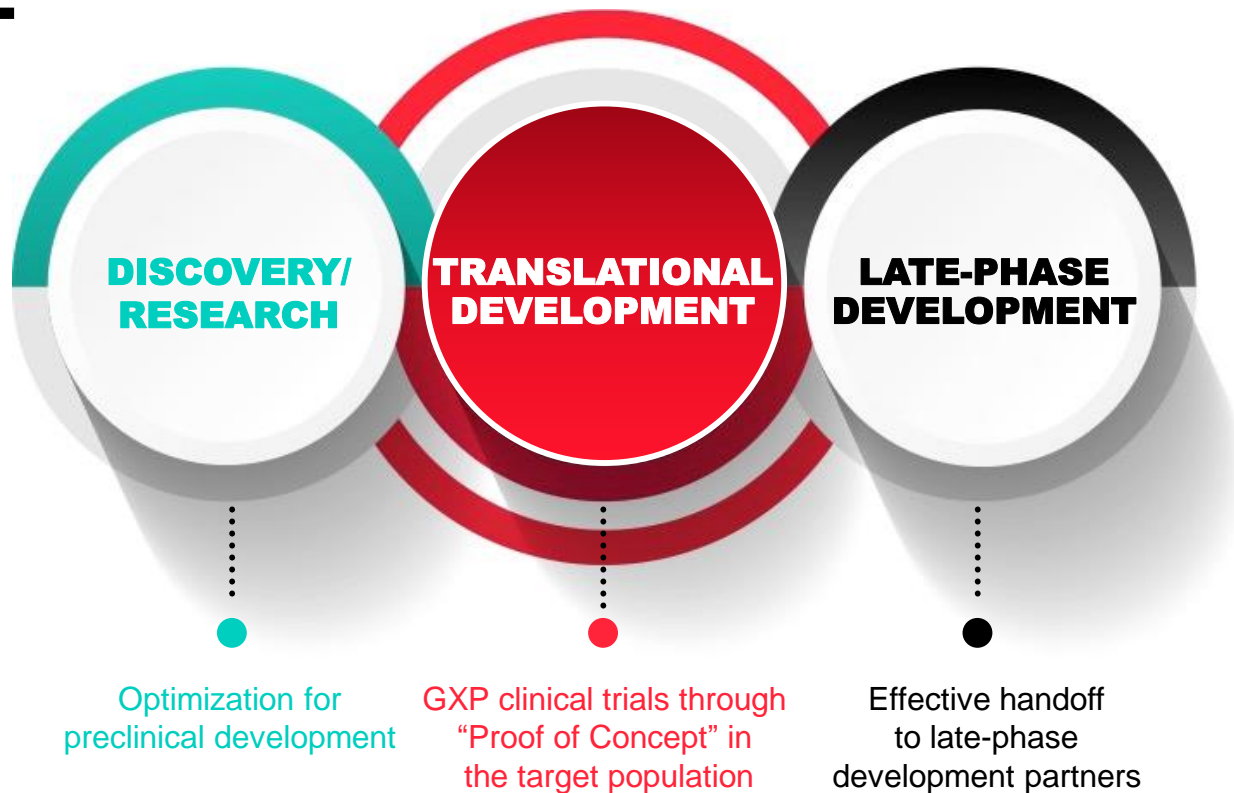


**TUBERCULOSIS**

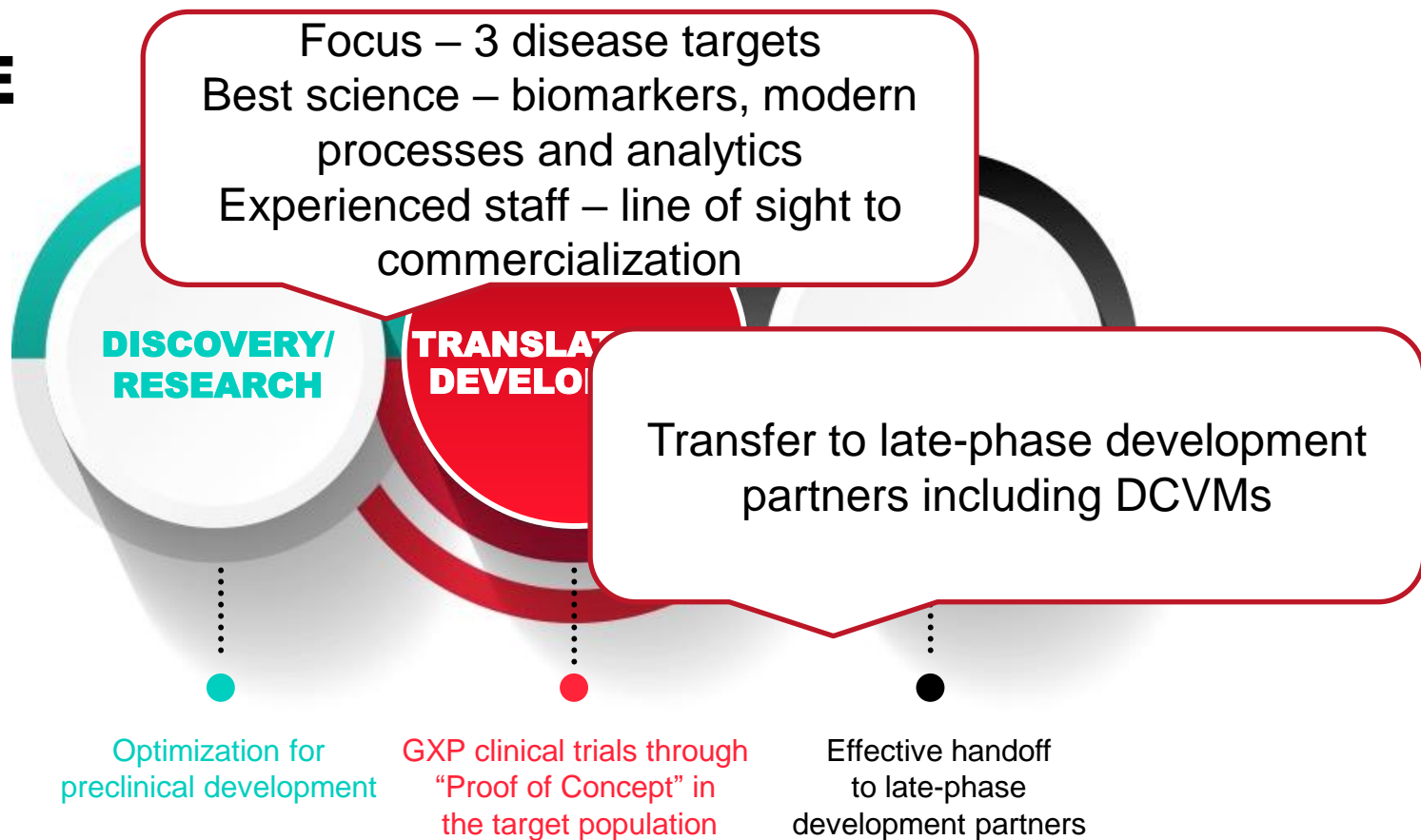


Accelerate the end  
of the tuberculosis epidemic

# / 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

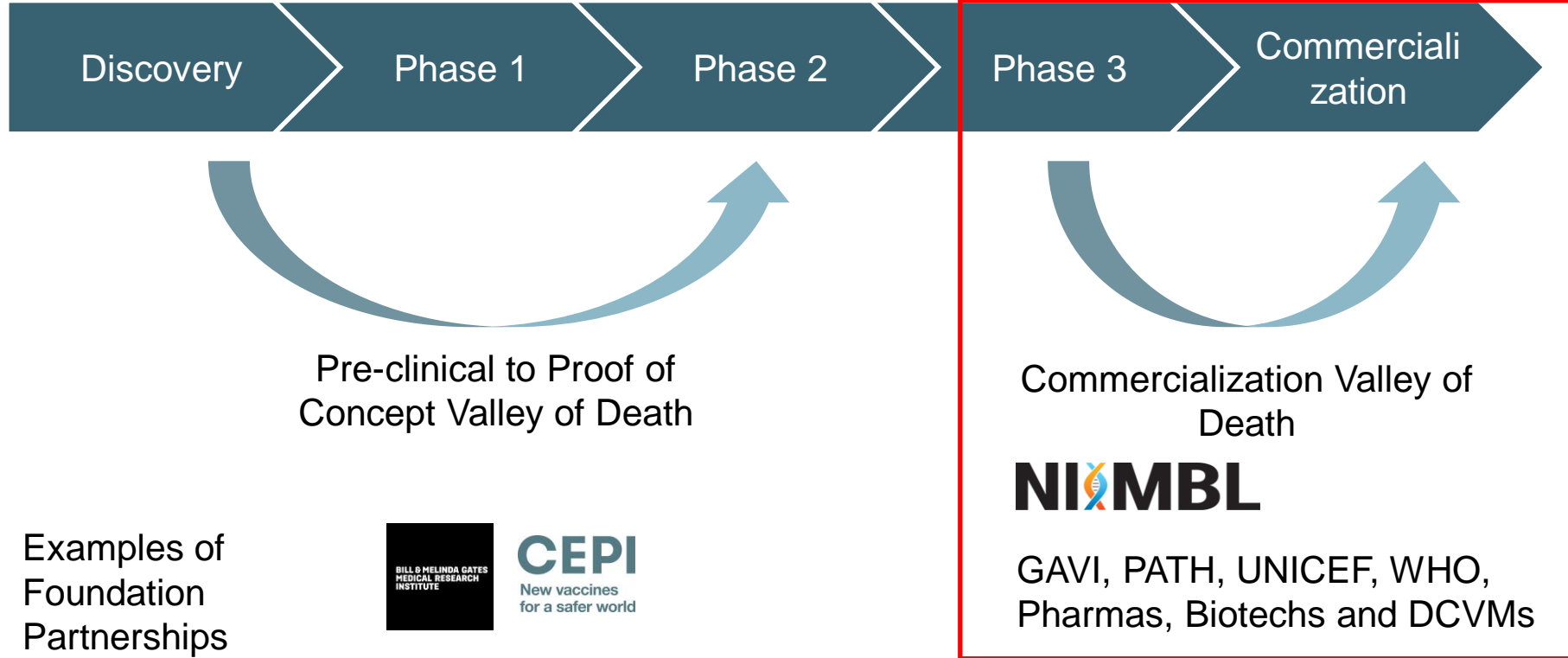
Patrick Florent  
leading Working  
Group on  
Sustainable  
Manufacturing

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



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



*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 world leading biopharmaceutical manufacturing

Ray Prasad (BMGF) will lead effort to identify projects

technologies 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

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

# NEVOLINE ACTURING

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Pre-clinical to Proof of  
Concept Valley of Death

Commercialization Valley of  
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Foundation funding  
Univercells through  
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commercialize platform

# 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.,

**fer** and **pro**

formulation, and

**erations**

**capability building**

, process dev., medical/P

Ensuring continued high quality is our number one priority!

QA/QC, line

Need to ensure a well trained workforce

Need appropriately staffed and skilled National Regulatory Authorities

## Central / Network considerations

① Discovery and early clinical development

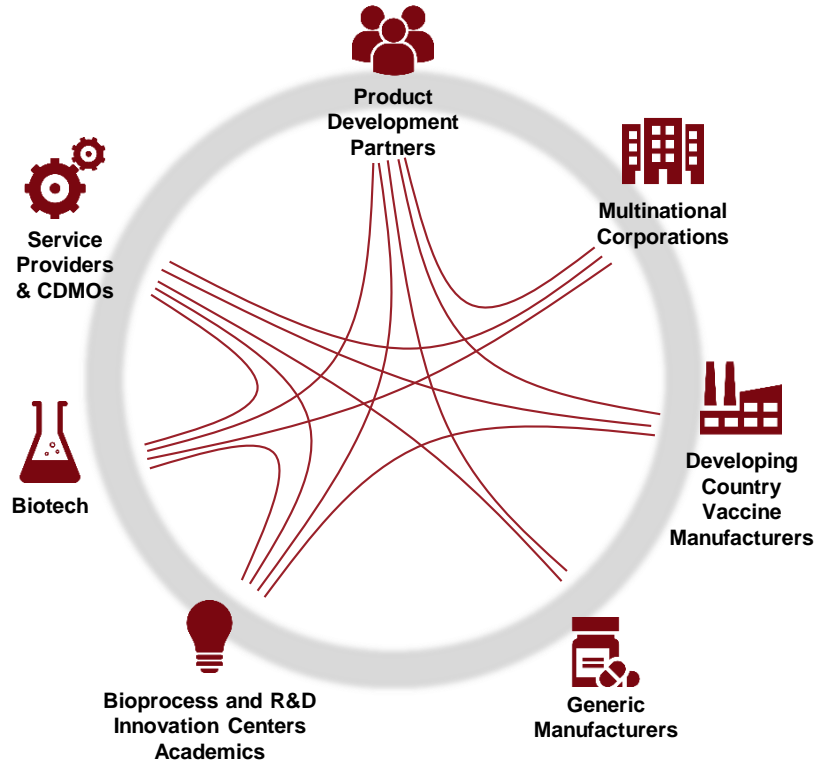
② CMC and analytic process development

**Government** buy-in and support (including policy)

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

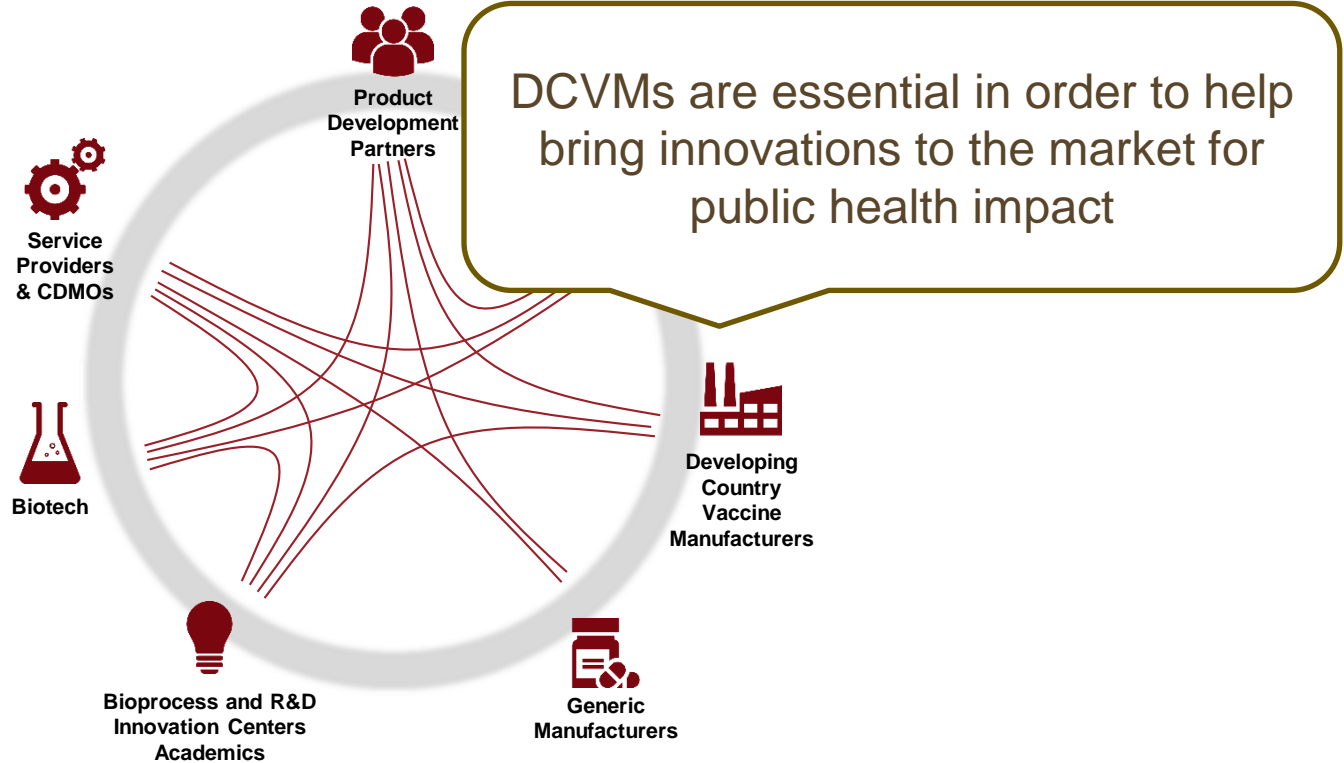
⑤ **Vaccine procurement systems**

# OUR ABILITY TO ACHIEVE IMPACT IS DEPENDENT UPON PARTNERSHIPS





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■ THANK YOU!

谢谢

Terima kasih

متشكرم

धन्यवाद

Danke

Cảm ơn bạn

Dank u

감사합니다

شكرا

ขอบคุณ

Gracias

Obrigado

Merci