ACCELERATING VACCINE DELIVERY AND DEVELOPMENT

Evolving Vaccine Ecosystem Technologies and Partnerships

David Robinson
Bill & Melinda Gates Foundation
WE SUPPORT VACCINE RESEARCH AND DEVELOPMENT IN PURSUIT OF OUR CORE GOAL

To ensure a secure and sustainable supply of consistently high-quality vaccines that meet the demands of local markets:

- Have the characteristics and packaging which enable maximum coverage by local healthcare workers.
- Meet WHO prequalification standards (or equivalent).

All countries and individuals can access vaccines whenever needed.

Varied by market to account for ability to pay and need for financial incentive to spur development.

Within WHO definition of a "fully immunized child".
WE UTILIZE A PARTNER NETWORK TO ACCELERATE TECHNOLOGIES THROUGH TWO VALLEYS OF DEATH

Discovery ➔ Phase 1 ➔ Phase 2 ➔ Phase 3 ➔ Commercialization

Pre-clinical to Proof of Concept Valley of Death

Examples of Foundation Partnerships

GAVI, PATH, UNICEF, WHO, Pharmas, Biotechs and DCVMs
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

DISCOVERY/RESEARCH
Optimization for preclinical development

TRANSLATIONAL DEVELOPMENT
GXP clinical trials through “Proof of Concept” in the target population

LATE-PHASE DEVELOPMENT
Effective handoff to late-phase development partners
Focus – 3 disease targets
Best science – biomarkers, modern processes and analytics
Experienced staff – line of sight to commercialization

Transfer to late-phase development partners including DCVMs

Optimization for preclinical development
GXP clinical trials through “Proof of Concept” in the target population
Effective handoff to late-phase development partners
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 to 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

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

Patrick Florent leading Working Group on Sustainable Manufacturing
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- Pre-clinical to Proof of Concept Valley of Death
- Commercialization Valley of Death

Examples of Foundation Partnerships:
- GAVI, PATH, UNICEF, WHO, Pharmas, Biotechs and DCVMs
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.

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, pharmas 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 NIUMBL TO SET UP A COLLABORATION FOR GLOBAL HEALTH

The National Institute for Innovation in Manufacturing and Biopharmaceuticals (NIIMBL) was developed under the US National Institute of Standards and Technology (NIST) to drive innovation in manufacturing and biopharmaceuticals.

How we want to work together:

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

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

Ray Prasad (BMGF) will lead effort to identify projects.

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

Foundation funding Univercells through proof of concept

Univercells exploring partnerships to commercialize platform

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Highly intensified, fully integrated modular manufacturing platforms

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- Rapid deployment of production capacity

Low capital costs of new modular facilities lowers barrier to entry for regional and local manufacturing
TECHNOLOGIES ARE ONLY ONE ELEMENT OF ACCELERATING DEVELOPMENT: HOLISTIC UNDERSTANDING IS REQUIRED

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

Central / Network-level considerations
1. Discovery and early clinical development
2. CMC and analytic process development
TECHNOLOGIES ARE ONLY ONE ELEMENT OF ACCELERATING DEVELOPMENT: HOLISTIC UNDERSTANDING IS REQUIRED

Manufacturer considerations

1. Materials sourcing for supply chain and analytic process development
2. Ingredient and process development (clinical trials, formulation, and process development)
3. Tech transfer and process validation
4. Bulk, formulation, and analytical manufacturer considerations
5. Local infrastructure (transport, utilities)
6. Government buy-in and support (including policy)
7. Health sciences infrastructure and support (technical service providers, plant design, air and water handling)
8. Vaccine procurement systems

Ensuring continued high quality is our number one priority!

Need to ensure a well trained workforce

Need appropriately staffed and skilled National Regulatory Authorities
OUR ABILITY TO ACHIEVE IMPACT IS DEPENDENT UPON PARTNERSHIPS
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Service Providers & CDMOs
Biotech
Bioprocess and R&D Innovation Centers
Academics
Product Development Partners
Developing Country Vaccine Manufacturers
Generic Manufacturers

DCVMs are essential in order to help bring innovations to the market for public health impact.
THANK YOU!

Terima kasih

धन्यवाद

Danke

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Obrigado

Gracias

Merci

Cảm ơn bạn

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