Capacity Building: Multiple global agencies involved in strategic dialogue to support regional vaccine manufacturing ecosystem

- Technology transfer and IP
- Research & Development
- Talent development
- Access to finance
- Market design and demand intelligence
- Regulatory strengthening
- Agenda-setting and coordination
- Infrastructure development

Source: PAVM Framework for Action, 2022 (Version1); PAVM Market Design and Demand Intelligence Workshop, June 2022
Developing Countries Vaccine Manufacturers Network

23rd Annual General Meeting
Pune, India
20-22 October 2022

Jicui Dong (MS, PhD, MBA)
Unit Head, Local Production and Assistance Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division
World Health Organization
Building and sustaining capacity for production of quality vaccines to improve access and health security

Resolution WHA74.6 on *Strengthening local production of medicines and other health technologies to improve access* is adopted

**Strengthening ecosystems for quality and sustainable local vaccine manufacturing**
- Policy coherence
- Financing
- Incentives
- Human capital development
- Supply of raw materials & equipment etc.

**Developing human capital** to ensure quality and sustainability
- Holistic training workshops on key factors for successful local production

**Providing PQ and EUL-related specialized technical assistance** to facilitate attainment of WHO PQ/EUL

**Nurturing partnerships, collaborations and synergy**

World Local Production Forum
Enhancing access to medicines and other health technologies

Local Production and Assistance Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division

World Health Organization
Biomanufacturing Training Initiative to improve LMIC biologics production efforts

- Upskill technicians, engineers, scientists & managers through didactic, hands-on training and placement
- Support WHO hub and spoke model for production of biologics (mRNA hub first one)
- Establish a global network of biomanufacturing training initiatives between
  - Global Hub at Ministry of Health and Welfare, Republic of Korea
  - Partner Hubs through training institutions in biomanufacturing
  - Regional training hubs
  - Online learning programmes
- Ensure inclusiveness and gender equality in science and biomanufacturing in particular
Developing Countries Vaccine Manufacturers Network

Annual General Meeting
20 to 22 October 2022
Pune India

Sushant Sahastrabuddhe
Associate Director General
Clinical, Assessment, Regulatory, Evaluation (CARE)
Framework for IVI's strategic roadmap for 2022-2026

**Vision**
Developing countries free of suffering from infectious disease

**Mission for impact**
Discover, develop and deliver safe, effective and affordable vaccines for global public health

### Innovative capabilities

**Research Institute**
- **Lab Research**
  Advance the science and identify new candidates for research within high burden target disease areas

**Collaborative partnerships**
- **Laboratory Collaboration**
  Strengthen global vaccine community through international cooperation and education

**Product Development**
- **Vaccine Development**
  Develop new vaccines and conduct clinical trials for infectious diseases affecting underserved populations
- **Epidemiology and Surveillance**
  Contribute to sourcing and adequate use of global vaccine and AMR data
- **Vaccine Effectiveness**
  Conduct large scale trials in priority regions for infectious diseases affecting underserved populations

### Flexible operations

**International Expansion**
- **Scale global footprint**

**Inclusive and responsive governance**
- **Future-proof governance**

**Enablers**
How we succeed

**Our vision and mission**
Why we exist

**Our pillars**
What we do

**Bigger and Better**
strengths and capabilities

**Pursue opportunistic actions**

**Amplify the Core**
IVI has built a strong network across Africa, Asia and Latin America that continues to grow across development and epidemiology work.

- **20+ projects** in 28+ sites creating ~1000 jobs
- IVI Europe Regional office in Stockholm, Sweden Sept 2022
- IVI Austria Country office in Vienna, Austria To open in November 2022
- 3 Collaborating Centers In Ghana, Madagascar, and Ethiopia
- Typhoid
- Cholera
- Other (AMR, COVID-19, Chikungunya, etc.)
IVI provides translational and support services to accelerate vaccine development

*We can cater to potential partners to select the activities that align to our shared goals*

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### Cross-Functional Activities

- **IVI develops and supports:**
  - Translational Hubs
  - Innovation Vaccine Research Centers
  - Globalization Centers

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### Vaccine Development Services

#### Pre-Clinical Study & Support
- Material production, test & release for toxicology studies
- Protocol dev.
- CMO/CRO identification

#### Process & Analytical Dev.
- Scalable & optimized processes for candidate Ag
- Analytical methods for qual. testing
- *In vivo* animal studies

#### Clinical Dev. & Regulatory Support
- Assay Validation & Clinical Samples Evaluation
- Tech Transfer Support
- Mfg. Support
- IPDP & CDP development
- Clinical trial implementation & management in HIC & LMIC
- Regulatory affairs consultation

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### Diseases

- iNTS
- Group A strep
- SFTSV
- Shigella
- Hepatitis A, B
- Tuberculosis
- HAdv-55
- COVID-19
- Paratyphoid A
- Zika
- Hantavirus
- Pulmonary Syndrome (HPS)
- Lassa fever
- MERS
- Invasive Non-typhoidal Salmonella (iNTS)
- MERS-CoV
- Chikungunya
- Schistosomiasis
- Typhoid
- COVID-19
- Cholera
- COVID-19
- Human Papilloma Virus (HPV)
- Hepatitis E
- Cholera
- COVID-19
- Typhoid
- Cholera
- COVID-19
- RSV
- GAS
- Shigella
- AMR

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**IVI also provides Project Management service tailored to the needs across the value chain.**
IVI, an International Organization and a partner in Development

Vaccine development
• IVI has led the fight against cholera in LMICs for 20 years with 90% of the global OCV stockpile (3 tech transfers completed) and developed a new-generation typhoid conjugate vaccine (3 tech transfers and WHO PQ expected mid-2023)
• Launched PDP partnerships with multiple DCVMs to take vaccine candidates ahead in development

Regulatory
• Through SIVAC initiative, strengthened the establishment and functioning of National Immunization Technical Advisory groups (NITAGs)

Capacity building
• Capacity building for surveillance and clinical trials in multiple countries in Africa and Asia ★ Case study on Nepal clinical site capacity building published
• Antimicrobial resistance (AMR) program: building disease surveillance capacity, collecting and analyzing retrospective AMR data in 12 Asian countries: Bangladesh, Bhutan, India, Indonesia, Laos, Myanmar, Nepal, Pakistan, Papua New Guinea, Sri Lanka, Timor Leste, and Vietnam

Training
• IVI’s International Vaccinology Course: >3,000 vaccine professionals from LMICs trained annually
• Global Training Hub for Biomanufacturing (GTH-B): introductory training program on biomanufacturing, as part of the supported by the South Korean Ministry of Health and Welfare (MoHW) and WHO
• IVI Collaborating Centers
• IVI Fellowship Program
Capacity Building: Manufacturers

VACCINE SECURITY
Sustained, uninterrupted supply of affordable vaccines of assured quality

- Long-term competition & affordability
- Diverse & local mfg base
- Back-up supply capacity
- Mitigate individual supplier risk & quality assurance risk
- Encourage innovation, R&D

Engaging manufacturers

- Invite to tenders, pre-tender meetings, supplier evaluation, regular contacts w. awarded suppliers, annual Vaccine Industry Consultations

Healthy industry
- Increased # suppliers in tenders

Multiple suppliers
- Procured from 34 suppliers (out of 45 supplies with WHO PQ)

Safety & quality
- Technical assessment & quality monitoring by WHO

Affordable
- ~ US$ 300 annual saving (competitive pricing)

Tier pricing
- Procured for 123 countries
Capacity Building: Eco-system

Countries

- Vaccine Procurement Practitioners Network (VPPN)
- Vaccine Procurement Practitioners Exchange Forum (VPPEF)
- Strategic Vaccine Procurement Assessment Toolbox
- Strategic Vaccine Procurement E-learning Course

Manufacturers

- Provide global market intelligence and information on procurement processes
- Encouraging manufacturers to join UNICEF’s tender
- Inform manufacturers of vaccine forecasts and demand specifics

Regions

- AU declaration to produce 60% of Africa's vaccines on the continent by 2040
- UNICEF works with Alliance Partners to leverage various mechanisms to bolster manufacturing on the continent
- ASEAN Leaders’ Declaration on Vaccine Security & Self-Reliance (AVSSR) --- Regional Strategic & Action Plan for AVSSR 2021-2025
- UNICEF works with partners around strengthening vaccine procurement capacity (ASEAN)
Vision statement
A world in which epidemics and pandemics are no longer a threat to humanity

Mission statement
Accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need

Prepare for known epidemic and pandemic threats
Transform the response to the next novel threat
Connect to enhance and expand global collaboration

100 day aspiration
To develop a safe and effective vaccine in 100 days from the moment that a pathogen is sequenced and/or the need for a vaccine is recognised to initial availability for use.
CEPI’s aspiration is to develop a vaccine in 100 days from alert trigger to a vaccine available for use.

**Challenges for Equitable Access:**
- Volatility of outbreaks, demand and timing
- Unknowns around the disease
- Complex interconnected systems

**Opportunities for Manufacturers:**
- Sustainable business models across both response and routine products
- Versatile technical capabilities and capacity
- Strong regional, multi-functional systems

**Laboratory Network – equipped throughout with standards & assays**
**Epidemiological studies and funding for local clinical trials**
**Manufacturing preferred partners’ capabilities strengthened and tech transfer**
**Regulatory strengthening of harmonised regulatory processes and reliance**
**Indemnity and Liability Provisions for Outbreaks**

We acknowledge this goal is incredibly ambitious and have established it as a north star, recognizing that with vision and collaboration, great things are possible.
Gavi’s proposed four-pillar strategy to support sustainable African Regional Manufacturing

<table>
<thead>
<tr>
<th>1</th>
<th>Coordination &amp; prioritisation of antigens</th>
<th>Support coordination of initiatives and shape product portfolio initiatives: Use Gavi’s voice to advocate for solutions that will lead to sustainable new market entrants, including through setting a clear vision of which antigens should be produced by new entrants to ensure a sustained demand</th>
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<tbody>
<tr>
<td>2</td>
<td>Market shaping principles</td>
<td>Implement changes to Gavi’s Healthy Markets Framework and Gavi Product Menu criteria to better value regionally diverse products and facilitate new entrants</td>
</tr>
<tr>
<td>3</td>
<td>Demand assurance</td>
<td>Work with African Union and Gavi supported African countries to encourage continental solidarity through expressed demand for African produced vaccines, sending signal of political commitment while preserving country product choice</td>
</tr>
<tr>
<td>4</td>
<td>Financial support</td>
<td>Craft an advance market commitment that would award a financial incentive for African vaccine manufacturers successful at bidding for and producing Gavi procured doses across an agreed set of antigens designed over two phases in 2022/2023</td>
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Panel Discussion
CAPACITY BUILDING – HARNESSING HUMAN CAPITAL: PEOPLE AND TALENT DEVELOPMENT STRATEGIES

DCVMN 2022

Julia Kuhn
THE FOUNDATION’S FOCUS ON WORKFORCE DEVELOPMENT

Why

COVID-19 has spurred the deployment of large sums of capital and major multilateral involvement in building vaccine manufacturing capacity in LMICs.

Lessons learned show tech transfer and quality by design (QbD) as two bottlenecks.

Need

In the near-term a talent pool is needed to support facility expansions.

For the longer term, there is a need to support a broader vaccine ecosystem of talent development from strategies to hands-on training.

How

Understand DCVM needs

Train via innovative and accessible materials/ programs.

Build an ecosystem by piloting “training the trainer” initiatives and other education & industry linkages.
The foundation has selected a small group of global and local partners to pilot programs to strengthen the ecosystem. The key findings from the NIIMBL needs assessment highlight:

- Manufacturers recognize need for increased trainings and are interested in accessing curriculum developed by outside organizations.
- There is an opportunity to strengthen the relationship between education and industry—initiatives aimed at partnering these stakeholders can strengthen the pipeline of qualified job candidates and ensure transfer of knowledge.
- A variety of methods will be important—a combination of theoretical and hands-on training will be required to adequately upskill employees and meet workforce demand and strong training strategies are critical to implementation.

DCVMN and NIIMBL are building a workforce directory to inform manufacturers of global training resources.
Key considerations for developing a talent strategy

Linking people to business objectives

Amanda Zehnder
Senior Organization Development and Change Management Advisor – CVIA
People decisions are business decisions

Talent strategy supports business goals

It looks at talent as a system within an organization

Links business success to human capabilities

- What skills, knowledge, and experience do our people need to be successful in their role?
- If our people cannot do ______, we will fail.
Key strategy components

Competency assessment – what behaviors are required for success?

Talent acquisition and development approach – rent, buy, grow talent

Job design – who is doing what?

Holistic approach to learning – training is only one part
Examples of rent, buy, or grow

Rent – Engage consultants, outsourcing, temporary workers

- Expertise you need once or occasionally
- Necessary but not part of your core business
- There is not enough need for an employee

Buy – Hire employees with required credentials, skills, knowledge, experience

- Competencies needed are readily available in the job market
- Credentials are required to perform the job
- Competencies require long periods of time to develop

Grow – Develop employees to gain the required skills needed for the job

- Competencies needed can be trained and developed quickly
- Skillset required are unique to your organization or not available on the job market
- Work is directly linked to your success and can’t be outsourced
Holistic approach to employee learning

Beyond training

**Organizational Culture**
- Supports continuous learning and growth mindset
- Invests in talent strategy

**On-the-job support**
- Constructive feedback, mentoring and coaching are practiced

**Talent management practices**
- Do we plan for the:
  - Right skills/people
  - Right place
  - Right time
  - Right rewards

**Training program**
- Fit for purpose with the talent strategy
Example of growth mindset – Microsoft*

1. **Focus on continuous learning.** Microsoft CEO, Satya Nadella, has challenged Microsoft’s employees to transition from “know-it-alls to learn-it-alls.”

2. **Reframe the response to failure.** Learning from failure and applying those learnings to future projects is the route to success and mastery.

3. **Foster collaborative working.** Creating a company where people recognize the power of working together, rather than apart, in separate teams and specialisms, is essential for a growth mindset culture.

4. **Encourage respectful questions.** The cross pollination of ideas is crucial to innovation.

5. **Leaders that model a growth mindset.** It’s impossible to establish a growth mindset culture in any organization without the buy-in and commitment of influencers and leaders.

DCVMN
23rd Annual General Meeting
Global Equity and Timely Access:
COVID-19 & Beyond

Q & A