Developing Countries Vaccine Manufacturers Network

Annual General Meeting
Capacity Building Panel – Connect to Protect
Pune India

October 22, 2022 Christina Liu LIUC@WHO.INT



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

Regulatory strengthening

Agenda-setting and coordination



Developing Countries Vaccine Manufacturers Network

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

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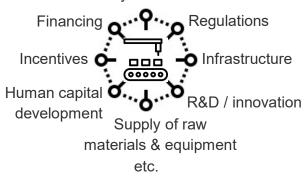


Building and sustaining capacity for production of quality vaccines to improve access and health security

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



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



Developing human capital to ensure quality and sustainability





Holistic training workshops on key factors for successful local production









Providing PQ and EULrelated 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







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





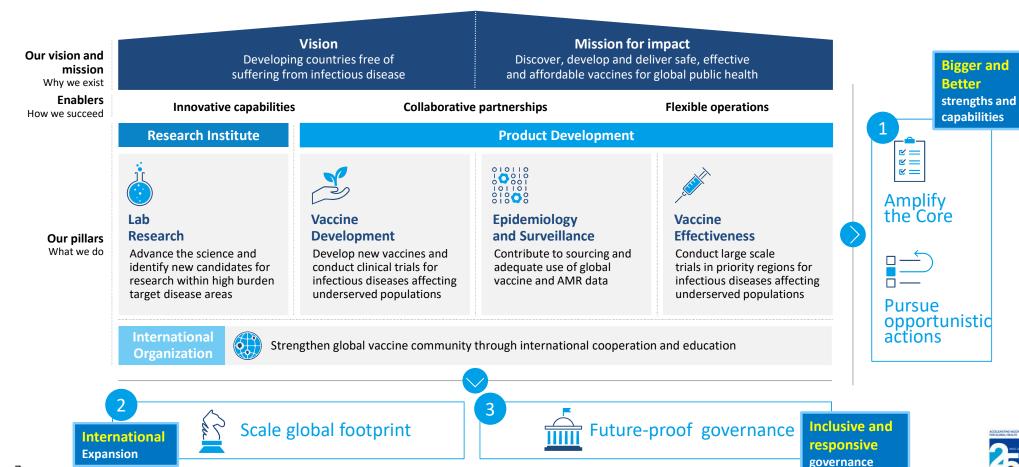


Developing Countries Vaccine Manufacturers Network

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



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

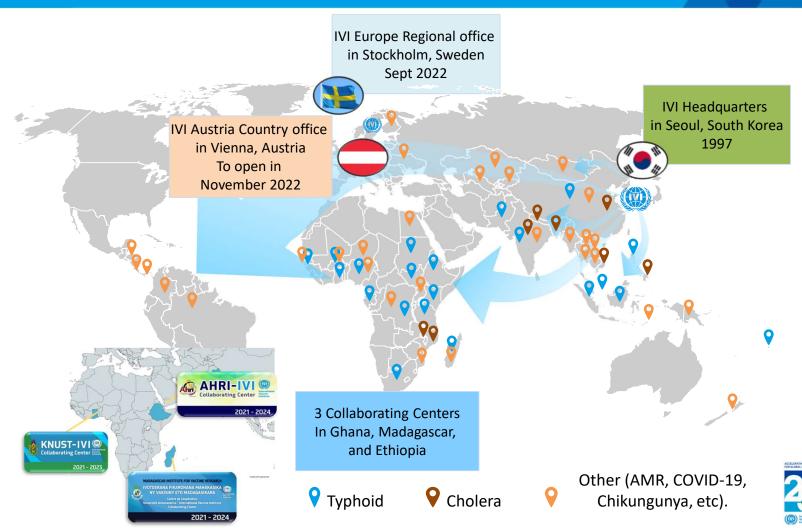


in

28+ sites

creating

~1000 jobs



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

| | Discover | | Develop | • | Deliver | Epi | i. Surveillance |
|---|---|---|---|-----------------------------|---|---|---|
| | Material production, test & release for | Assay Validation & Clinical Samples Evaluation | Critical assay development & optimization | Health Economic Study | Field-based data collection incl. costing | Epidemiology/ Observational Study Support | Protocol dev. incl. definition of endpoint, bio investigation, & database |
| Pre-Clinical Study & Support Process & Analytical Dev. | toxicology studies | | Method validation according to ICH guidelines | | & willingness to pay | | Prevalence & incidence est. of infection/disease severity |
| | Protocol dev. CMO/CRO | Tech Transfer Support | Clinical sample evaluation in GCLP lab | | Global/country analyses incl. invest., budget impact, cost- | | Data for decision on vaccine |
| | identification | | Candidates & process transfer to CMOs & stability plan dev. | | | | introduction Site preparedness for Ph.3 trial |
| | Scalable & optimized processes for candidate Ag | Mfg. Support | Process scale-up & ensuring of commercial-scale mfg. & vaccine candidate supply | | effectiveness, demand & disease burden | AMR Monitoring | effectiveness study AMR assessment & public database creation |
| | Analytical methods for | Clinical Dev. & Regulatory Support | IPDP & CDP development | Policy & Advocacy Research | | | Mass vaccination campaign |
| Dev. | qual. testing | | Clinical trial implementation & management in HIC & LMIC | Modeling | Vaccine impact & disease risk mapping etc. | Vaccine Impact & Effectiveness Study | Vaccine intro through health authorities |
| | <i>In vivo</i> animal studies | | Regulatory affairs consultation | | | | Real-life vaccine performance assessment |
| iNTS Group A strep SFTSV Hantavirus Hepatitis A, B Tuberculosis HAdV-55 COVID-19 Invasive Non-typhoidal Salmonella (iNTS) MERS-CoV Chikungunya Schistosomiasis Typhoid COVID-19 COVID-19 MERS Invasive Non-typhoidal Salmonella (iNTS) Chikungunya Schistosomiasis Typhoid COVID-19 COVID-19 Micro-needle array (MAP) Hep-B | | sis | Human I Hepatiti Cholera COVID-1 | | Typhoid Cholera COVID-19 RSV GAS Shigella AMR | | |

Cross-Functional Activities

IVI develops and supports:

Translational Hubs Innovation Vaccine Research Centers Globalization
 Centers



^{*} 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 COCOA CCCDP



Regulatory

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

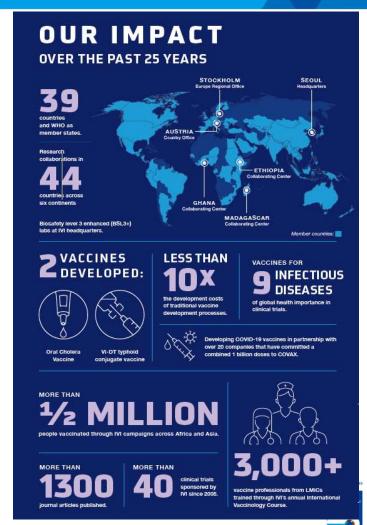
Capacity building

- 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







unicef for every child

Capacity Building: Manufacturers

VACCINE SECURITY

Sustained, uninterrupted supply of affordable vaccines of assured quality

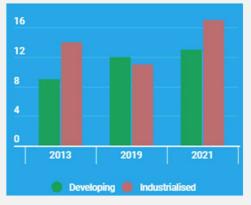
Long-term competition & affordability

Diverse & local mfg base

Back-up supply capacity

Mitigate individual supplier risk & quality assurance risk

Encourage innovation, R&D



Increased # awarded vendors from developing countries

Provide global market intelligence, long-term forecast

Share procurement principles & procurement process

Transparent on product menu, contract award, pricing, etc.

IONALE _

Engaging manufacturers

Invite to tenders,
pre-tender meetings,
supplier evaluation,
contacts w. awarded sur

regular contacts w. awarded suppliers, annual Vaccine Industry Consultations

Healthy industry

in tenders

Multiple suppliers

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

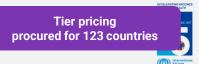
Safety & quality

Technical assessment & quality monitoring by WHO

Affordable

~ US\$ 300 annual saving (competitive pricing)

Tier pricing



unicef for every child

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 specfics

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)



CEPI

2.0

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



100 days

Alert trigger

Challenges for Equitable Access:

- Volatility of outbreaks, demand and timing
- Unknowns around the disease
- Complex interconnected systems

Laboratory Network – equipped throughout with standards & assays Epidemiological studies and funding for local clinical trials



Vaccine available for use

Opportunities for Manufacturers:

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

Manufactur'g preferred partners capabilities strengthened and tech transfer Regulatory strengthen'g harmonised regulatory processes and reliance

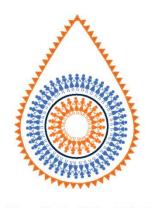
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Indemnity and Liability Provisions for Outbreaks We acknowledge this goal is incredibly ambitious and have established it as a north star, recognizing that with vision and collaboration, great things are possible

Gavi's proposed four-pillar strategy to support sustainable African Regional Manufacturing

| 1 | Coordination & prioritisation of antigens | 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 |
|---|---|--|
| 2 | Market shaping principles | Implement changes to Gavi's Healthy Markets Framework and Gavi Product Menu criteria to better value regionally diverse products and facilitate new entrants |
| 3 | Demand assurance | 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 |
| 4 | Financial support | 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 |





DCVMN 23rd Annual General Meeting

Global Equity and Timely Access: COVID-19 & Beyond

Panel Discussion



CAPACITY BUILDING – HARNESSING HUMAN CAPITAL: PEOPLE AND TALENT DEVELOPMENT STRATEGIES

DCVMN 2022

Julia Kuhn

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THE FOUNDATION'S FOCUS ON WORKFORCE DEVELOPMENT



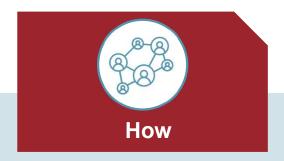
COVID-19 has spurred the deployment of large sums of capital and major multilateral involvement in building vaccine manufacturing capacity in LMICs.

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



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



Understand DCVM needs

Train via innovative and accessible materials/ programs.

Build an ecosystem by piloting "training the trainer" initiatives and other education & industry linkages.

A MULTI-PRONGED APPROACH IS NEEDED TO STRENGTHEN THE MANUFACTURING ECOSYSTEM



The foundation has selected a small group of global and local partners to pilot programs to strengthen the ecosystem

Key findings from the NIIMBL needs assessment highlight:

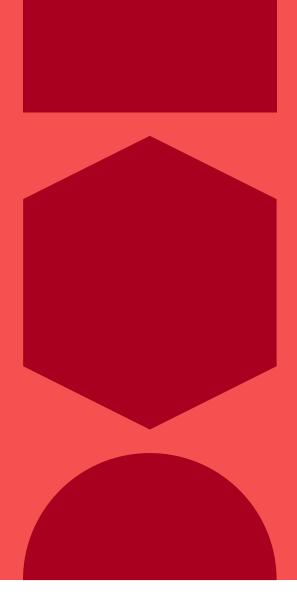
- Manufacturers recognize need for increased trainings and are interested in accessing curriculum developed by outside organizations.
- There is an opportunity to strengthen the relationship between education and industry -Initiatives aimed at partnering these stakeholders can strengthen the pipeline 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

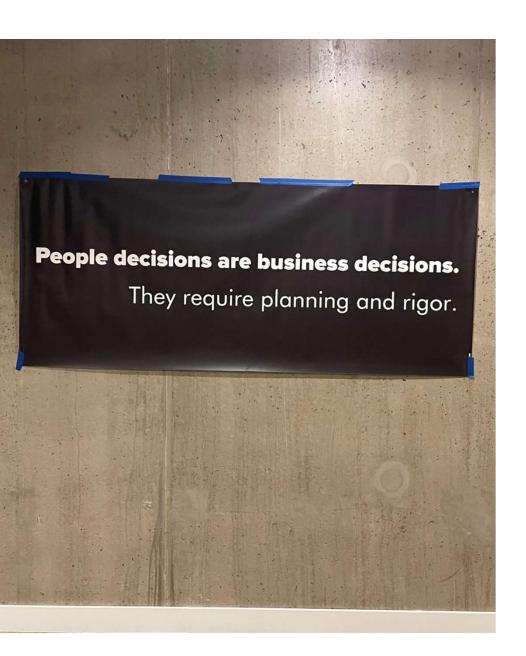
Talent strategy supports business goals

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 Talent management practices Supports continuous Do we plan for the: learning and growth mindset Right skills/people Invests in talent strategy Right place Right time Right rewards On-the-job support **Training program** Fit for purpose with the talent Constructive feedback, mentoring and coaching are strategy practiced



Example of growth mindset – Microsoft*

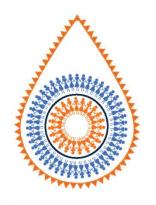
- **1. Focus on continuous learning**. Microsoft CEO, Satya Nadella, has challenged Microsoft's employees to transition from "know-it-alls to learn-it-alls."
- **2. Reframe the response to failure**. Learning from failure and applying those learnings to future projects is the route to success and mastery.
- **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.



^{*5} Secrets to Microsoft's Growth Mindset Success - https://thriveglobal.com/stories/5-secrets-to-microsofts-growth-mindset-success/







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Q&A