26th Annual General Meeting
CEO's Report

DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

Rajinder Suri
DCVMN International
Bali, Oct. 29, 2025

The Goal

To strengthen and enrich vaccine manufacturers through advocacy & elite training programs on technological excellence, capacity building and acting as a cohesive force to foster strategic partnerships and funding streams!

01

Geopolitical Changes & Global Health Challenges

Geopolitical Changes & Global Health Challenges

Impact of Geo-political Developments

- Pandemic Agreement signed.
- US Administrations decision to withdraw funding from WHO has had a spiralling effect.
- Not only the financial impact but also on technical and scientific inputs, vital for rapid response to any Public Health Emergency of International Concern.

Global Health Program Disruption

- Loss of funding for critical programs: The US previously contributed ~12-15% of WHO's budget. The exit is affecting programs for HIV/AIDS, Tuberclosis, Malaria and Polio as also on the manpower affecting PQ timelines.
- Reuced Global Monitoring Capactiy: WHO's ability to detect and respond to Emerging Health Threats is compromised. Without US support early warning systems and coordinated responses to outbreaks may be delayed.

GAVI Funding

- Huge impact of `USD 3 billion on GAVI 6.0 budget of USD 11.9 Billion
- Vaccine procurement budget reduction from USD 7 billion to USD 4.9 billion is likely to have direct bearing on immunisation programs and vaccince manufacturers.

Pandemic Agreement

The Agreement

Finally, 78th World Health Assembly adopted the landmark Pandemic Agreement on May 20th, 2025 after three years of negotiations, to make the World more equitable & safer from future Pandemics.

The Pandemic Agreement sets out principles, approaches and tools for better international coordination to strengthen the global health architecture for pandemic prevention, preparedness and response.

01

IGWG 1 & 2

Intergovernmental Working Group (IGWG) formed by the member states with reference to Resolution WHA 78.1 which established the open ended IGWG on the WHO Pandemic Agreement have had two meetings on July 9-10, 2025 and September 15-19, 2025 wherein they have taken up Article 12 dealing with PABS and are addressing key aspects of the Annexes however, not reopening any clauses of the Agreement for debate.

02

Next Steps - IGWG 3

The third meeting of IGWG is scheduled to be held on November 2-7, 2025 in hybrid format at WHO headquarters in Geneva . DCVMN is representing your constituency as relevant stakeholder.
We are fortunate to have Dr. Madeleine Heyward, Vice Chair, WHO Pandemic Fund, Australia and Dr Nedret Emiroglu , IGWG Head of Secretariat, for the Session on Pandemic Fund during this AGM scheduled tomorrow.

03

02

Achievements & Key Engagements 2025

Score Card 2025

46

Member Companies

8

Expert Working Groups

1

Technology Transfer Training Delivered

2

New VR Modules in Development

3

Publications in reputed journals

2

Novel Initiatives Launched

- Quality by Design
- Manufacturing Science

Tech-Transfer Training 5

Location

A real life GMP experience organised at one of the DCVMN member companies Panacea Biotec Limited, India from September 8th - 13th, 2025

Organisation

A true example of resillience and high-level of execution witnessed against all odds caused by the natural calamity including torrential rains and washing away of roads. Scientists from 4 WHO Regions worked directly with subject matter experts on Process and Method Transfers, ran practical simulations of full technology transfer workflows and shared excellent presentations, thanks to an effective leadership exhibited by Panacea Biotec team, so well coordinated by Prerna Kumar from DCVMN.

Outcome

12 fully trained professionals reverberating with confidence to disseminate the knowledge gained and share experiences with team mates in home countries.
The feedback was exuberance of expressions like: '*Everything is high-standard*', 'Lot of inspiration', 'An outstanding program!', ***'A hands-on program high-lighting the need to support the global mission of building stronger, more equitable vaccine manufacturing capacity in LMICs***.'

Next Tech Onsite Transfer Training Program (TTT6) is being organised at ICGEB, Trieste, Italy from December 15th - 19th, 2025.

Made for DCVMs by DCVMs

Quality by Design

Experts from member companies have developed an elite program duly supported by international experts on Quality by Design (QbD). It trains participants to apply QbD principles across all stages of vaccine facility and process development, to help learners design robust processes that ensure product quality, regulatory compliance, and manufacturing efficiency from the very start.

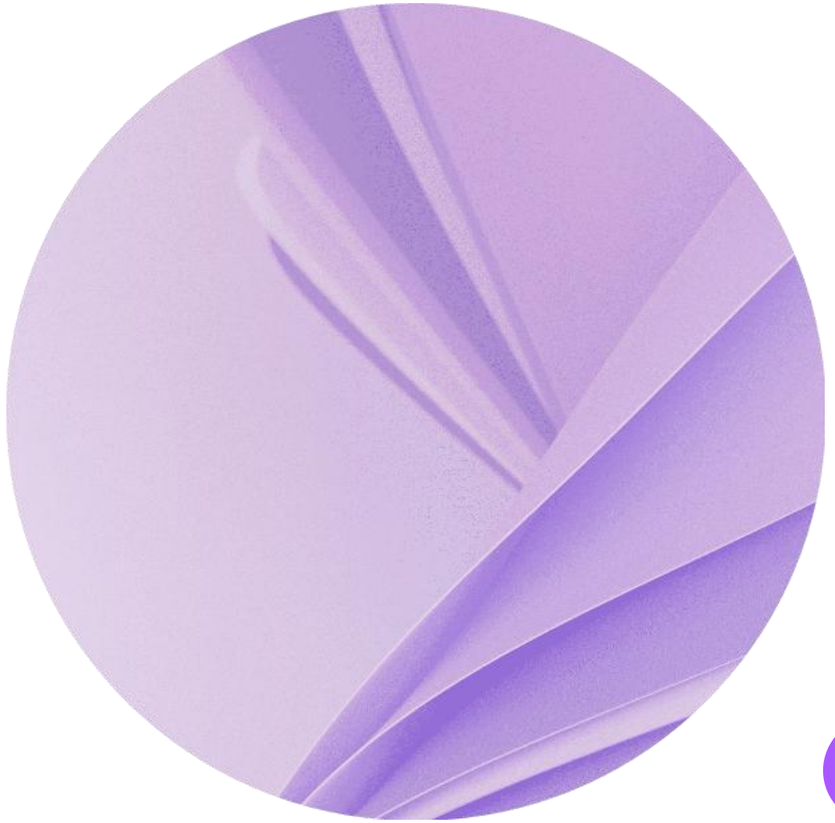
Virtual Reality

- First and only of its kind in the vaccine manufacutring space
- 3 modules already available and compatible with the two most common headsets: META Quest & Pico
- 2 new modules in development
  - Environmental monitoring techniques
  - Grade A/B aseptic behavior

Manufacturing Science

Subject Matter Experts(SMES) from member companies in consultation with international expert, have developed a course on Manufacturing Science. It provides essential scientific and technical training for early-stage vaccine development. Covering key topics: CQA identification, platform technologies, bioprocess optimization and analytical methods.

Quality by Design



01

Value Proposition

Recognizing that effective GMP compliance begins with robust process and facility design, the course focuses on the practical application of QbD principles to strengthen manufacturing development and regulatory alignment. By building skills in QbD methodologies, the course strengthens workforce readiness, creates clear pathways for process development and quality professionals and reduces company's dependence on external sources.

02

For Vaccine manufacturer

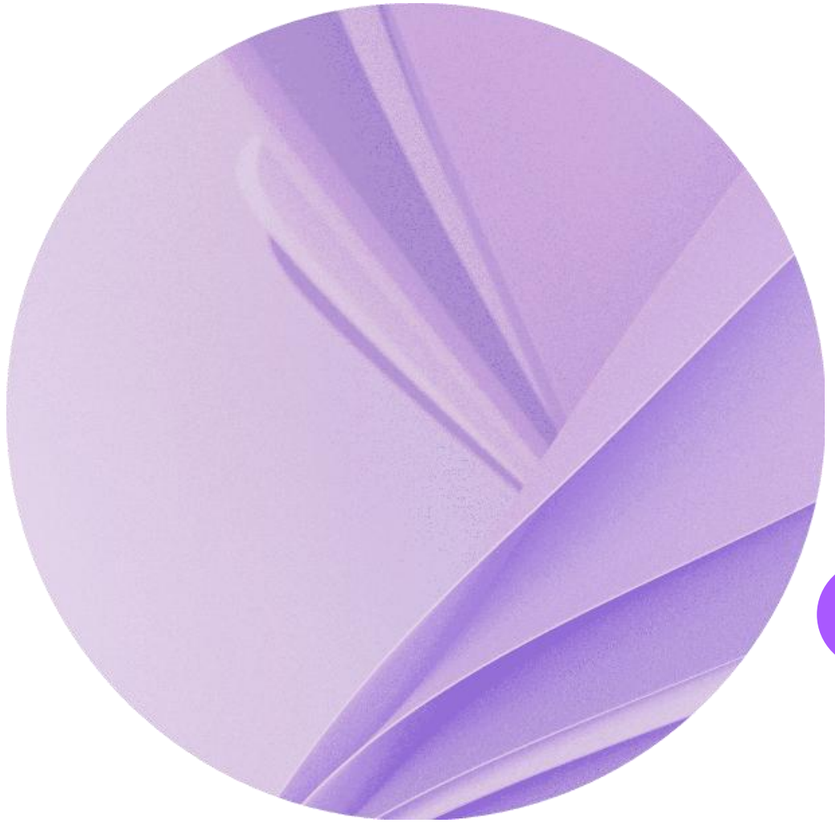
i. The participants are able to design from operational perspective a facility, ready for an engineering firm to design mechanically.
ii. They will be able to operationally develop a facility, ready for timely start-up after construction
iii. Will be able to systematically collect and store all operational information, to respond promptly to quests during all phases of erecting a facility.

03

Deliverable

The DCVMN QbD Course equips participants with the tools and methodologies to embed quality into every stage of vaccine manufacturing, from initial planning through the commercial launch

Manufacturing Science Group



01

Value Proposition

The MSG course develops core scientific competencies for early-stage vaccine R&D and applied process development. Designed & delivered by DCVMN member experts, the 4 day in-person program combines interactive lectures, case studies and applied problem-solving to create cohorts able to diagnose in-process failures, design robust experiments,and accelerate method validations. The course raises technical baseline across DCVMs, supports career pathways into higher-value technical roles, and strengthens the global partner ecosystem for technology transfer and co-development.

02

For Vaccine manufacturer

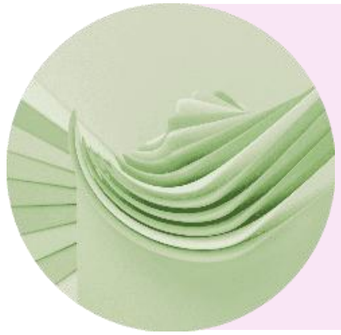
- The program converts recurring technical bottlenecks into sustained institutional capability at DCVMs.
- Strengthening local vaccine R&D and process development → equitable access and pandemic preparedness.

03

Deliverable

- MSG produces a DCVM workforce who delivers higher-quality analytical packages and more reliable process data, thus reducing qualification friction during technology transfer and co-development.
- Improved technical readiness shortens timelines for multinational projects and decreases rework, benefiting U.S.firms engaged in partnerships with DCVMs.
- The course builds mid-career technical expertise that U.S. members can tap for joint development, contract manufacturing, and expanded market engagement.

Key Achievements: 2025

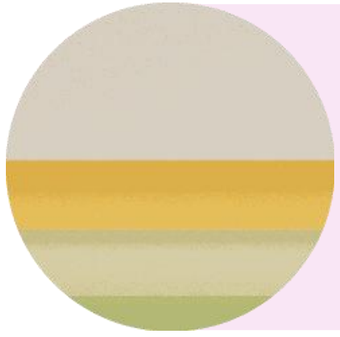


Signing of USD 5.5 Million contract with CEPI for DCVMN-INCLEN Project INNOVATE

After conceptualising and a persistent effort of over three years, DCVMN & INCLEN have signed an agreement with CEPI for the International Network for Vaccine Safety Surveillance (INNOVATE), an Integrated Population and Sentinel Hospital-Based Vaccine Safety Surveillance in Six Low and Middle-Income Countries!

Initiation of Pilot Poject on NET ZERO with UNICEF and Four Member Companies

DCVMN takes pride in entering into a strategic collaboratin with UNICEF to initiate a pilot project on Sustaianbility and Net Zero involving four of its member comapnies in Asia and LATAM. The learnings will be disseminated to the entire membership!



1st Collaboration with WIPO IP for Medical Innovation and Manufacturing Centre of Excellence (CoE)

DCVMN becomes the first international organisation to enter into a collaboartion with the Centre of Excellence, World Intellectual Property Office in Geneva to initate a successful training program on intellectual propoerty for 14 of its members!

02a

DCVMN-Inclen
Project INNOVATE

INNOVATE: In alignment with CEPI's 100 DAYS MISSION

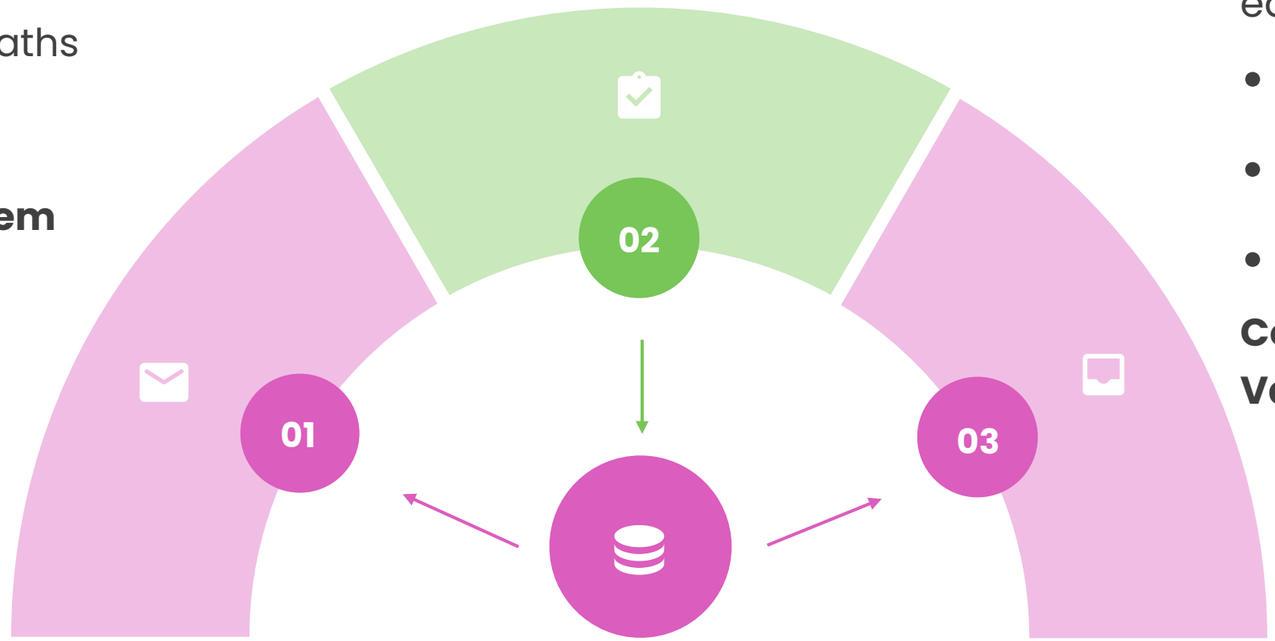
PREPARE

- Leveraging market forces
- Background rates for **AESI / AEFI** targeting different vaccine development platforms deaths and age stratified
- Establishment of **Active Vaccine Surveillance System (AVSS)** for **half a million population** representing

2 billion population

TRANSFORM

- Transformation through sharing data with **DCVMN** to pave the Pathways for **Rapid Vaccine Approvals**
- Site can become **platforms for Vaccine Trials**
- Strengthening **National AEFI Surveillance System**



CONNECT

Global Collaborations through emerging infectious disesases, equitable access and response

- **3 Continents**
- **6 Countries**
- **9 Sites**

Community, Researchers and Vaccine Manufacturers

02b

Sustainable Vaccine Manufacturing

Sustainable Vaccine Manufacturing: GHG Reduction Net Zero Roadmap and SBTi

01

UNICEF

Acts as an institutional partner supporting the project in alignment with its mission and strategic goals without direct involvement in financial or contractual arrangements.

02

DCVMN

Responsible for effective coordination of the project and managing institutional participation.

03

GTB

Formally designated as the exclusive technical consulting partner providing strategic and technical guidance throughout the exectuion of the project.

Sustainable Vaccine Manufacturing: GHG Reduction Net Zero Roadmap and SBTi

Technical Foundation

GHG Protocol-Compliant baselining with vaccine-specific emission factors and process mapping

Strategic Modeling

SBTi aligned decarbonization scenarios and roadmap with cost benefit optimization and risk assessment

Capacity Building

Sustainable knowledge transfer through interactive content documentation: manuals, whitepapers

Industry-first blueprint enabling 4 manufacturers to achieve SBTi validation with scalable methodology for global vaccine manufacturers.

02c

Leveraging IP

IP for Medical Innovation and Manufacturing CoE with WIPO

Global Security

Enhance global health security driven by need for self reliance post COVID.

Regional Manufacturing

Strengthen regional medical manufacturing in LMICs for pandemic preparedness.

Benefits

Economic benefits and reduction of reliance on imports (potential to access technology at a lower price).

03

Objectives Strategy & Road Map

Strategic Objectives

To support Immunisation Agenda 2030

A Global Strategy to Leave No One Behind

The World Health Assembly, with the support of countries and partners, has endorsed a new global vision and strategy, the Immunization Agenda 2030 (IA2030), to address these challenges over the period 2020-2030 and save over 50 million lives.

To equip vaccine manufacturers with latest tools

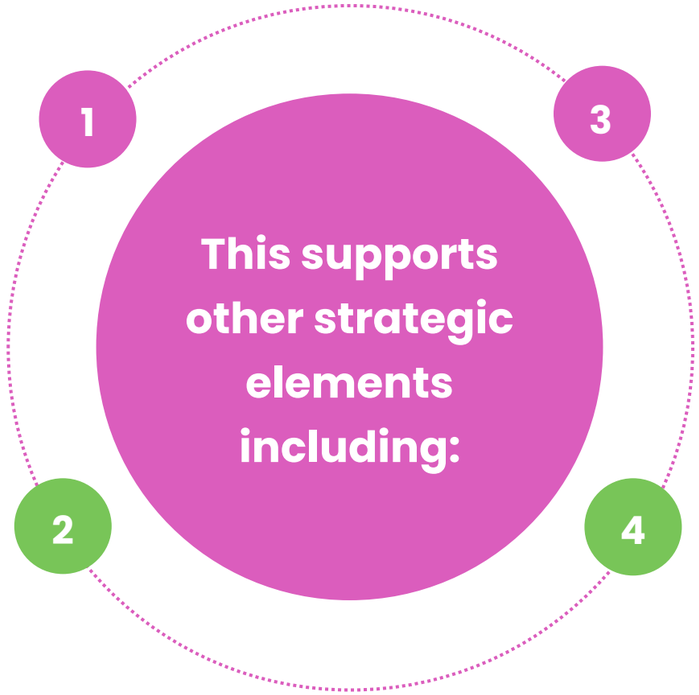
To equip vaccine manufacturers in Developing Countries with modern tools of Tech-Transfer Training, QbD, MSG and IP through high-end programs.

To be effective voice of DCVMs

To ensure sustainability and survival in these tough times by voicing genuine concerns of developing countries vaccine manufacturing constituency.

5 Year Strategy & Road Map

To provide sustinable, scaleable professional development via training for capability enhancement with focus on supporting the manufacturing and supply of high-quality vaccines in alignment with international standards!



1. Technical Support for Competency Building
2. Attainment and Maintenance of WHO Prequalification
3. Foundational Skill Building including direct application of concepts and/or hands-on practice.
4. Knowledge sharing activities through Subject Matter Expertiese shared with limited learner direct application or practice.

The Roadmap

Foundation Phase

- Hiring an L&D expert
- Perfecting the DCVMN TTT
- Evaluating of the DCVMN training offerings
- Launching the NIIMBL Training Directory
- Building new partnerships
- Creating of talent program framework and success metrics

Build Phase

- Business Modelling Consultancy for self sustainability
- Leveraging NIIMBL Training Directory
- Exploring Training certificate partnership and designing for talent development
- Creation of talent program framework and success metrics.
- Implement new course development or existing course improvements

Next Generation Phase

- **We have advanced and continue to expand our training programs: TTT & VR**
- **Developing new trainings: MSG, QbD and L&D working group. The goals set for this Phase - "Creation of a professional development community of practioners made up of training and professional development staff of member organizations."**

As the gaps in the Talent Program framework are addressed, we are able to identify the next wave of initiatives required to enhance the Talent Development program, such as:

- **Additional staff**
- **Negotiating with professional development providers on behalf of members for better pricing.**

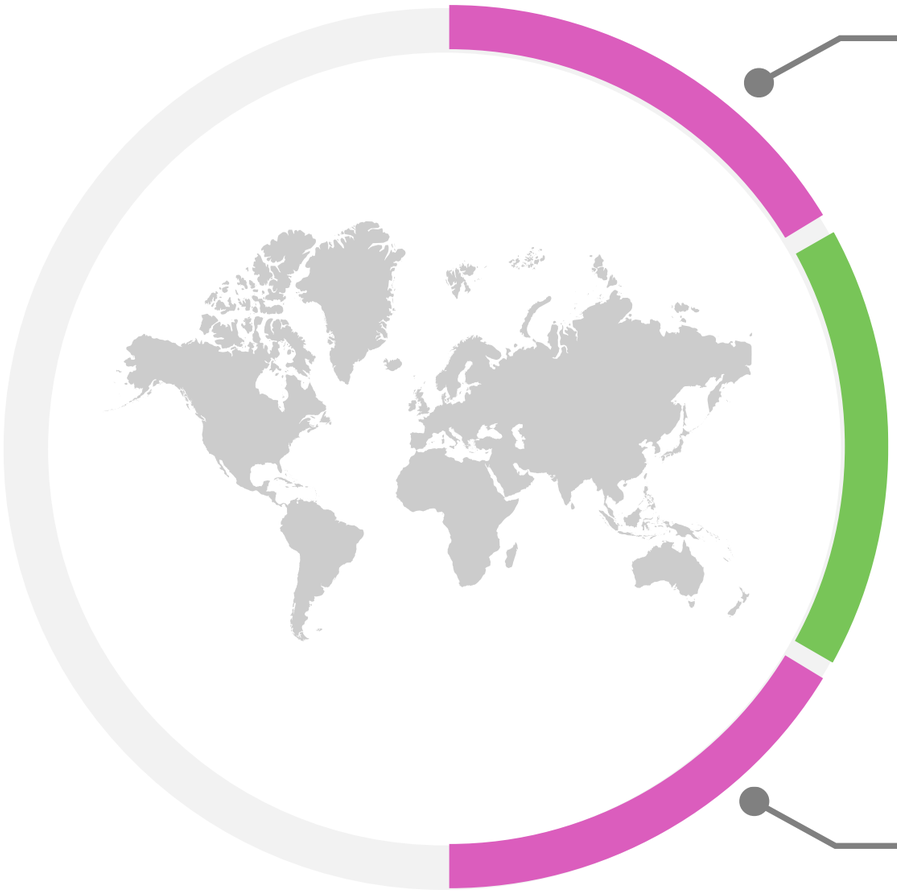
2023

2024

2025

2026-2027

Outreach & Advocacy-2025



>10 Member Companies Visited

>15 Conferences & Forums

>150 Meetings and Committee Sessions with IOs and Partners

DCVMN: Influence & Impact

World Health Organization

- WHO Prequalification Consultation
- Strategic Advisory Group of Experts (SAGE) on Immunization Meeting
- Technical Advisory Group on COVID-19 Vaccine Composition (TAG-CO-VAC)
- Product Development for Vaccines Advisory Committee (PDVAC)
- 7th General Meeting of WHO Network of National Control Laboratories for Biologicals (WHO-NNB)
- World Local Production Forum (WLPF)
- Intergovernmental Negotiating Body (INB)
- Identification, analysis and prioritisation of Combination vaccines – Engagement with DCVMN and IFPMA
- Global Network of Quality Control Laboratories for Pharmaceuticals (WHO-GNP)
- Public Consultation on WHO Measurement Standards for Biologicals
- Peer-review the WHO position paper on pneumococcal conjugate vaccines in infants and children under 5 years of age
- 2025 WHO MI4A Industry Data
- Informal consultation on WHO recommendations for the preparation, characterization, establishment and use of WHO international biological reference preparations (IBRP)
- Peer-review the WHO vaccine position paper on Herpes Zoster vaccines
- Peer-review Information-sharing agreement on vaccine quality data and lot release testing of Prequalified and Emergency Use Listed (EUL) vaccines
- Observer capacity for WHO Considerations in developing a regulatory framework for human cells and tissues and for advanced therapy medicinal products

UNICEF

- Effective participation: Vaccine Industry Consultation, Copenhagen
- Supply Chain & Net Zero
- Interaction with Supply Chain Working Group

Gavi the Vaccine Alliance

- GAVI Board
- Gavi PPC
- Virtual interaction with GAVI CEO, Dr. Sania Nishtar
- Presentation during GAVI replenishment
- Supply Chain Working Group

iMCM

- In-person participation in iMCM 2 & iMCM 3, held in Geneva & recently in Istanbul

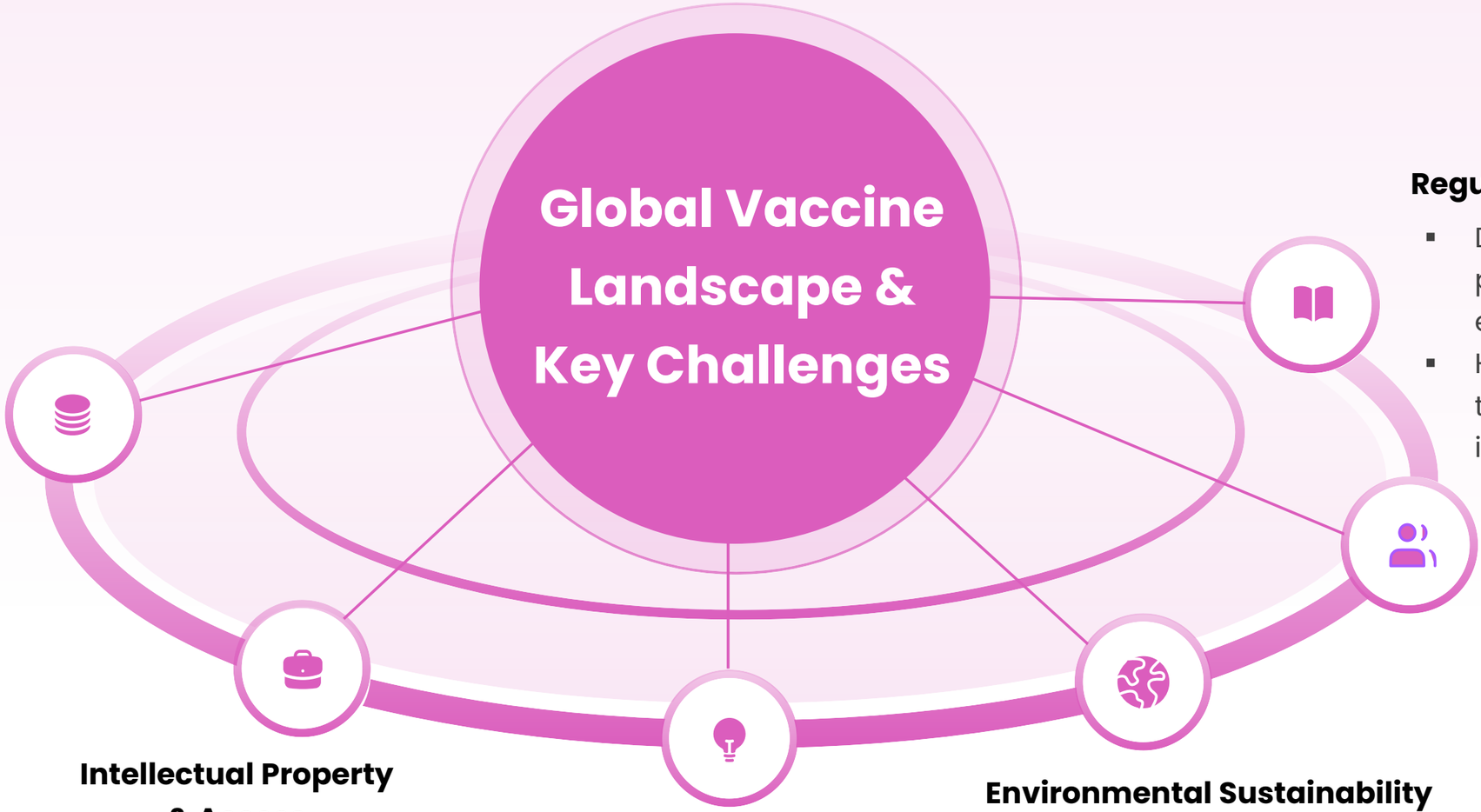
CEPI

- JCG
- Annual Product Review
- F2F meeting with CEO
- Entered into a 3 year agreement for Project INNOVATE by DCVMN-Inclen

04

Global Vaccine Challenges & DCVMN Initiatives

Global Vaccine Landscape & Key Challenges



Funding Squeeze & Market Uncertainty

- Donor fatigue and tighter public budgets → smaller, unpredictable grant pools.
- Procurement volatility reduces market visibility for manufacturers.

Intellectual Property & Access

Need for pragmatic IP approaches to enable wider manufacturing without discouraging innovation.

Technology Transfer & Manufacturing Capacity

- Growing demand for rapid tech transfer to build regional capacity.
- Gaps in tech-readiness, infrastructure and skilled personnel.

Environmental Sustainability

- Rising pressure to reduce carbon emissions across manufacturing and supply chains.
- Green transition requires capital, technical guidance and donor support.

Regulatory Harmonization

- Divergent regulatory pathways delay market entry.
- Harmonization shortens time-to-impact and increase confidence.

Collaboration is Essential

Peer partnerships accelerate practical solutions (tech transfer, regulatory support).

Our Actions to Resolve These Challenges

01

Healthy Industry Framework (HIF) WG

Launching the "Dashboard of Opportunities" for members to find funding opportunities, request support with proposal drafting and eligibility analysis, and access a matchmaking service.

02

DCVMN & WIPO IP Workshop

The two-day, in-depth training brought together professionals from 15 DCVMN member companies across Asia, Africa, and Latin America.

03

DCVMN Technology Transfer Training

We have conducted five successful tech-transfer training sessions. In total, we have trained >70 vaccine workforce members from 16 countries.

04

L&D WG

With a mission of capacity building and competency enhancement within DCVMN members, L&D WG is dedicated to focus on curating courses on Leadership, Communication and Quality Culture

05

Pharmacovigilance WG

Having sussessfully rolled out two publications, PV WG is now taking up the challenge to develop a manuscript on PV maturity Systems Analysis for wider dissemination

06

Intellectual Property (IP) WG Launching

The goal of the WG is to help member manufacturers transform legal and commercial knowledge into tangible results.

07

Regulatory WG

Realising challenges of time, cost and resources the focus of the RAWG is on CRP in collaboration with WHO and NRAs. A publication on PAcs has been submitted to a reputed journal.

08

Supply Chain WG

The team is working on Vaccine Packaging Optimization study and Sigle Use Technology as also trying to unravel the mystery of AI in vaccine supply chain with support from SMEs

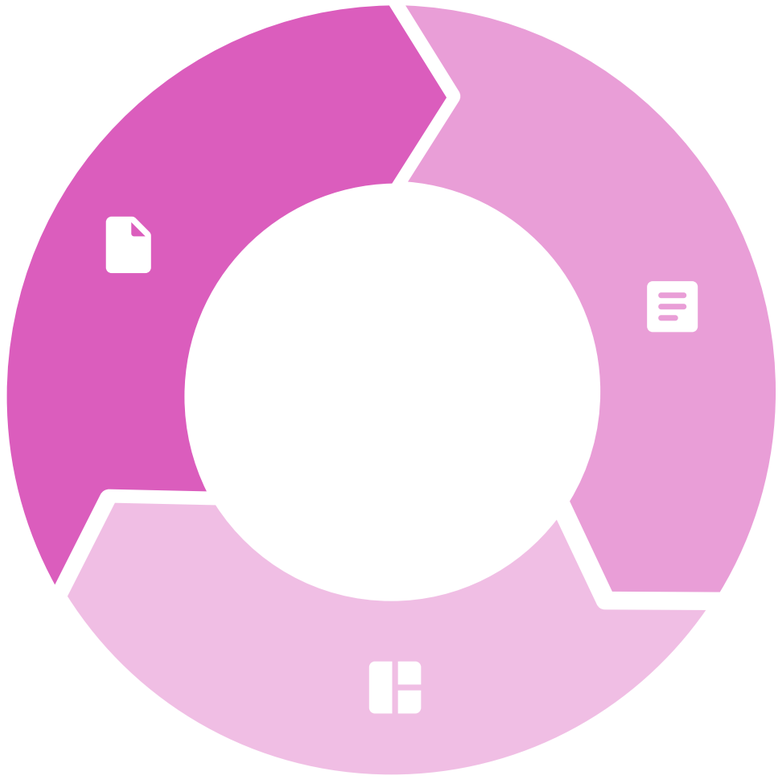
116 Collaboartions 2021-2025

South-South, 41

50% in 2024-25

5 new South-South collaborations in 2025

Importance: strengthens joint market entry plans, accelerates practical technology transfer, and builds mutual support networks for procurement and dossier readiness.



IOs, 41

54% in 2024-25

11 new collaborations between members and IOs and in 2025

Importance: Enables access to funding, pooled procurement channels and risk-sharing mechanisms that stabilise demand, and provides technical guidance.

North-South, 34

88% in 2024-25

12 new North-South collaborations in 2025

Importance: Opens opportunities for access to advanced CMO capacity, specialized know-how and potential co-development arrangements.

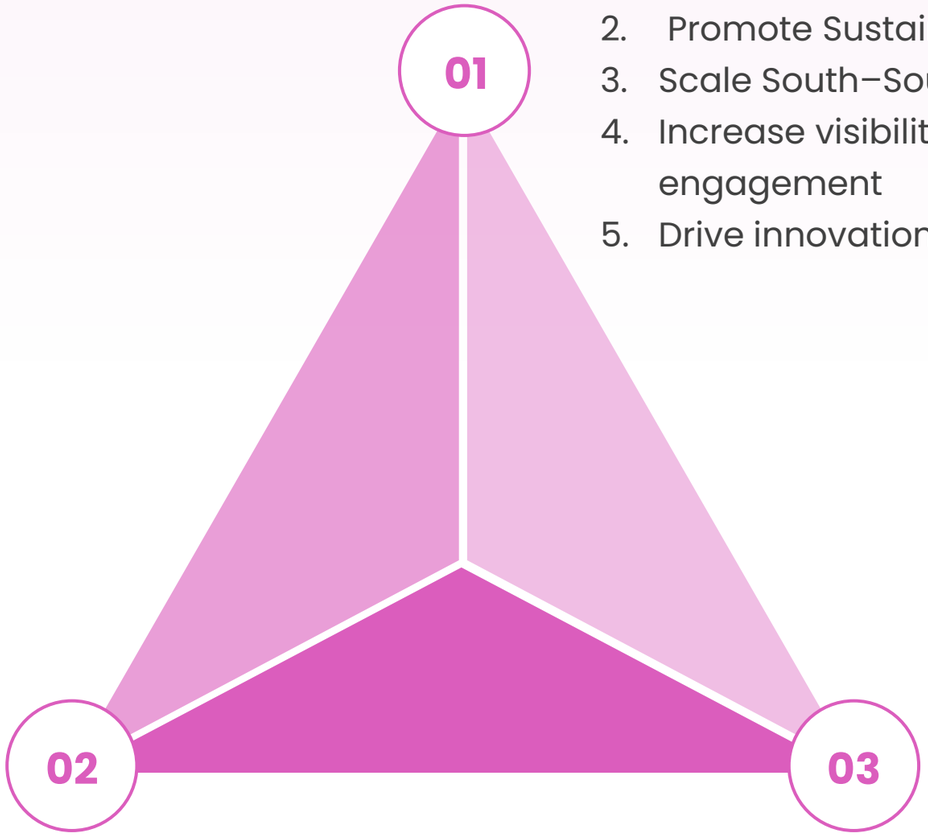
05

Way Forward

2026 Strategy

Sustainable Manufacturing

1. Advance regulatory & quality harmonization
2. Promote Sustainable & Net Zero Manufacturing
3. Scale South–South collaboration & regional hubs
4. Increase visibility through advocacy & member engagement
5. Drive innovation & collaborative R&D



Sustainable Financing

1. Advocate for Members' Market Access & Funding
2. Enable Industry Resilience (HIF)

Workforce Development

1. Build workforce excellence and L&D
2. Develop trainings for DCVMs by DCVMs

Thank you

We are the one true voice of DCVMs!

DCVMN
INTERNATIONAL
Developing Countries Vaccine
Manufacturers Network International