

# Developing Countries' Vaccine Manufacturers' Network International

Improving vaccination for all people



Developing Countries Vaccine  
Manufacturers Network

# Mission: our purpose and mandate



- To **protect all people** against known and emerging infectious diseases, by **improving the availability of high-quality vaccines** globally.

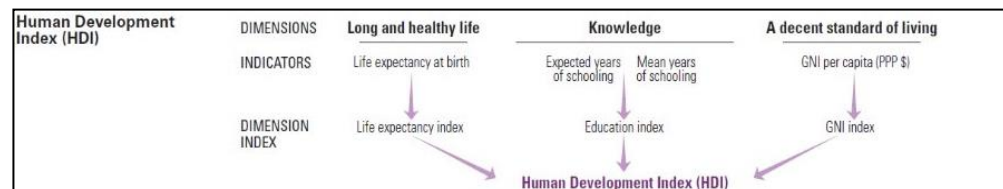
# DCVMN International

- It is a **voluntary, non-governmental, non-partisan, not-for-profit, public health driven** alliance of vaccine manufacturers, research and policy organizations from all over the world.
- Operates based on **principles of international scientific, technical and economic cooperation.**

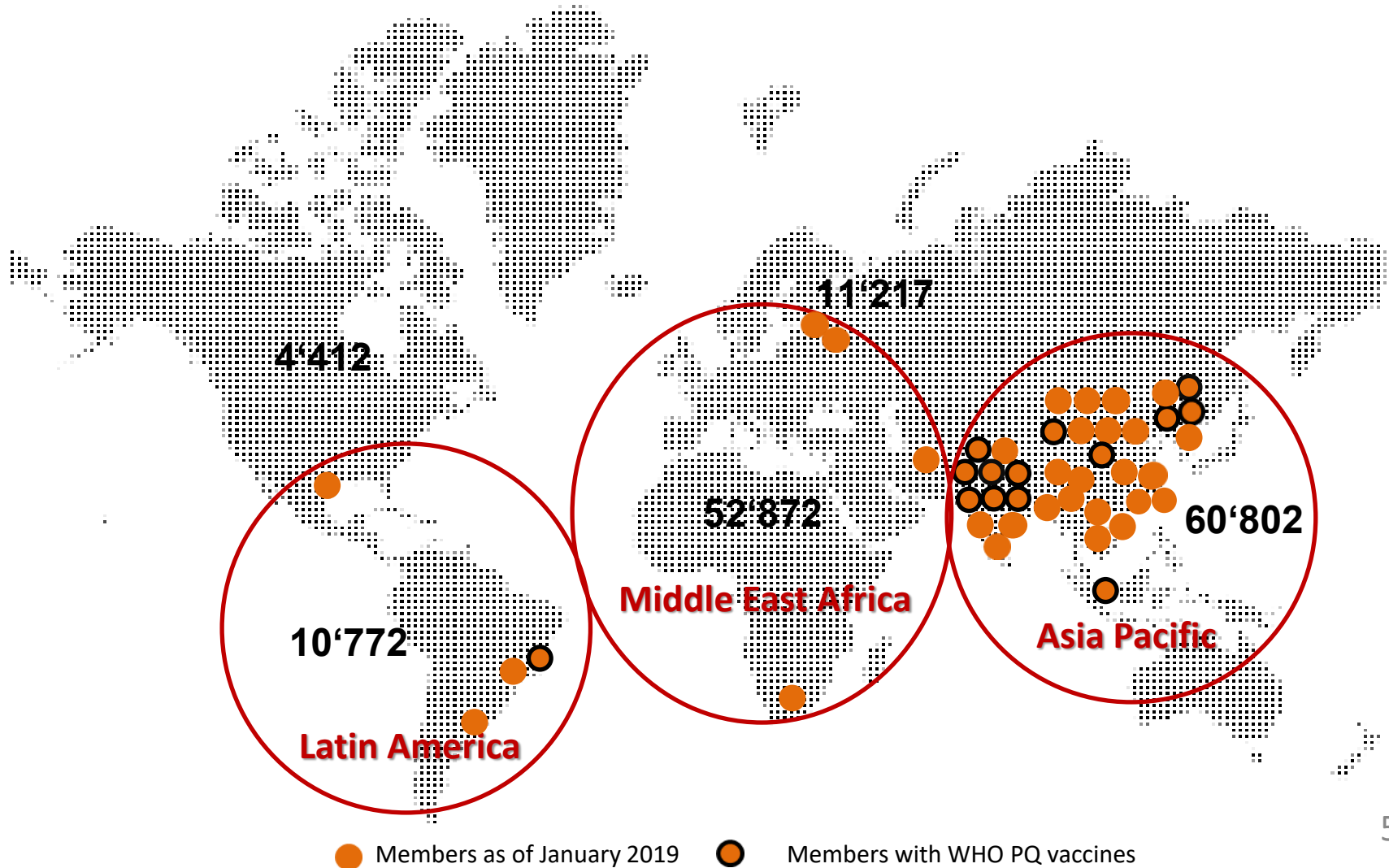
# Developing Countries Economies



- developing economies according to the UN & IMF
- transitioning to developed economy



# DCVMN 2019: 44 manufacturers from 14 countries/territories



number of birth cohorts 2015 regionally are indicated in black (x1000)

[http://www.who.int/immunization/monitoring\\_surveillance/data/en/](http://www.who.int/immunization/monitoring_surveillance/data/en/)

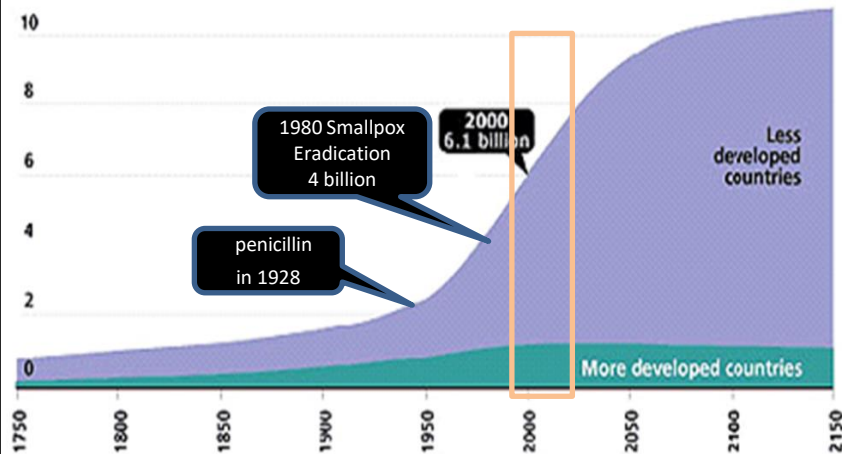


# Our Challenge : vaccination to all people

## Our Chance: partnerships

### *The developing world needs more vaccines*

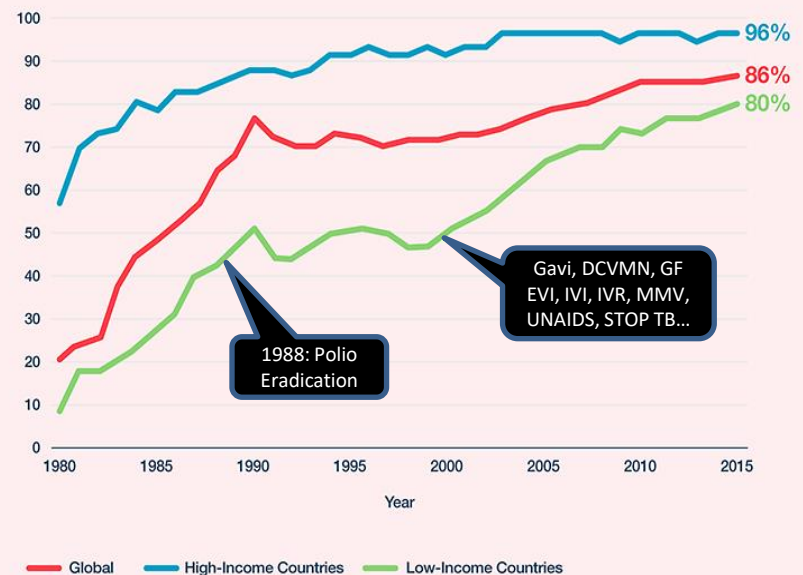
World Population Growth, 1750–2150  
Population (in billions)



Source: United Nations, *World Population Prospects, The 1998 Revision*; and estimates by the Population Reference Bureau.

### *Global Vaccination Coverage at Its Highest*

Coverage with three doses of diphtheria-, tetanus-, and pertussis-containing vaccines (DTP3), by country income levels, 1980–2015

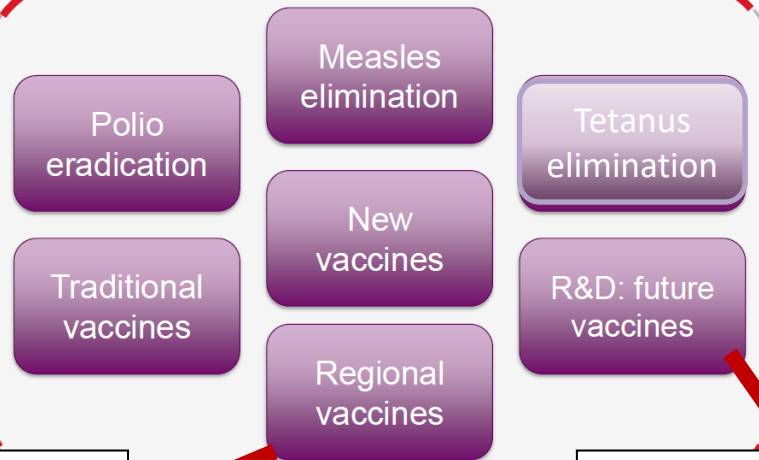


Source: WHO/UNICEF

<https://www.gatesnotes.com/2017-Annual-Letter>

# DCVMN Contributions to the Global Vaccination Landscape

Synergies and shared learnings



## DCVMs preventing regional infectious diseases

New conjugated  
Typhoid Fever vaccines



MenAfriVac™



Hepatitis E vaccine



Japanese  
encephalitis



Yellow Fever Vaccines



EV-71 Enterovirus,  
HFV



GAVI Alliance Board meeting  
Dhaka, 16–17 November 2011

## Outbreaks with epidemic potential

Ebola



MERS



LASSA



ZIKA



CCHF



NIPAH



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# Initiatives 2019-2021 to Support DCVMs



Our main 3 goals are to:

- A) build **technical capabilities** and strengthen capacity of MFs to produce and deliver quality vaccines across the long-term,
- B) proactively engage DCVMN members on priority issues shaping the broader landscape (e.g., **regulatory knowledge, supply chain**, etc.) and
- C) establish more systematic & **proactive dialogue with international bodies** to shape DCVM issues.

Interviews and extensive discussions were conducted with members and 6 initiatives were **recommended**:

1. **Training: Expand current QMS programs to include training on GMP, GCP, GLP, GDP, PV, etc.**
2. **Best-practice sharing:** foster peer to peer communication through expert working groups
3. **Advance regulatory convergence:** support efforts to new approaches on a regional basis
4. **Increase access to international expert consultants for needed ad hoc support**
5. **Engage MFs on new technology adoption through AGM**
6. Support for **pharmacovigilance (PV) projects to enhance vaccines safety** monitoring



# 1. Teach to Reach



Source: National Training Laboratories, Bethel, Maine

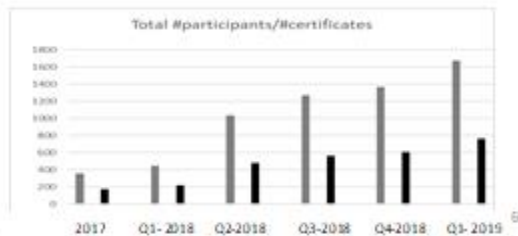
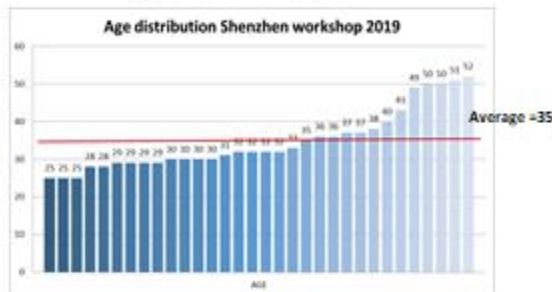
# 1. Training: Expand current QMS programs to include training on GMP, GCP, GLP, GDP, PV, and other issues

## Teach to reach

"the multiplier effect"



### Training on GDP and suppliers audits

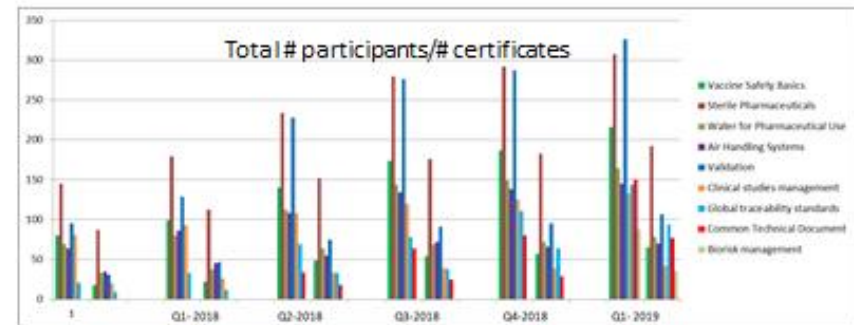


## E-Learning resources on DCVMN website

<http://www.dcvmn.org/-Knowledge-section->

- WHO Basic GMP modules
- ICH Quality guidelines
- UNICEF supply course (IFPMA)

E-learning platform  
UPGRADE YOURSELF NOW!



# Immersive learning: investing in people to create innovative mindset & enablement prior to “hands on”

## VR hands on training



3 «hands-on» main scenarios where VR training can impact operational capacity:

1. **Equipment operation**
2. **Emergency management**
3. **Laboratory (testing/formulation)**



## Training Chain: relay training



Imperial College  
London

- Focus on QC assays to improve technology /methodology, reducing risks and inspections
- Support QC Team training in a expert QC lab (NIBSC/ISS/ etc.) for new testing assays:
  - One “trainee” at a time (2-4 weeks), on a relay setting to build strong teams (3-5 people). Next trainee comes only when the previous returned and passed on the knowledge
- Enables common understanding of the whole process and team building and 3Rs, and sustainability

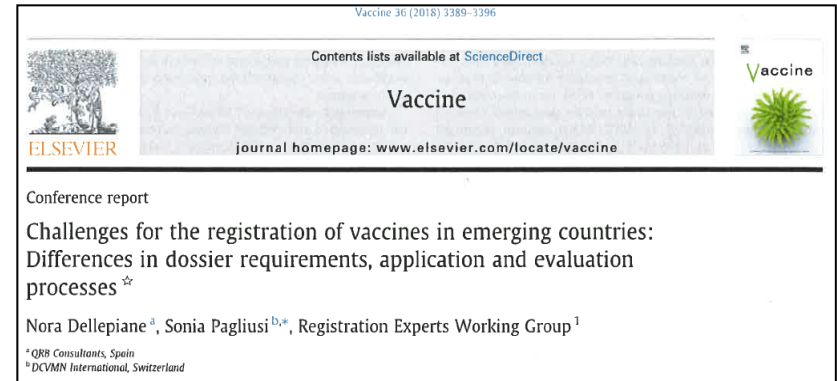
## 2. Expert Networking

- Enhance **best-practice sharing**, and peer to peer communications through expert working groups and hands-on training, as possible
  - Supply-chain experts working group
  - Vaccine Safety best-practices
  - QC assays & technologies
  - Formulation & filling expertise
  - Etc...

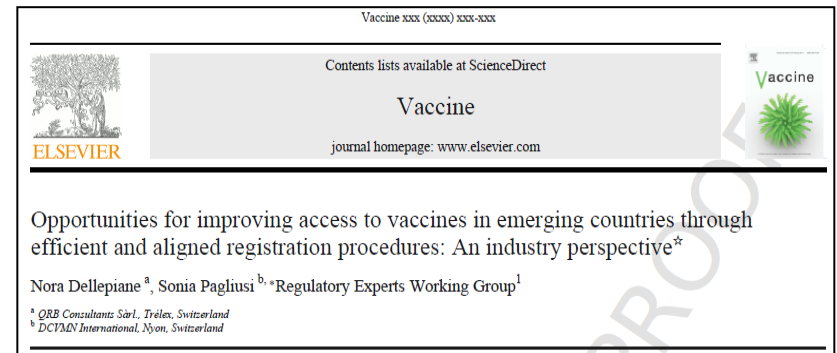
# 3. Foster dialogue to advance regulatory convergence approaches

Challenges to registrations were identified by an independent expert consultant and discussed with members

- ✓ Create **consensus among manufacturers from both DCVMN-IFPMA** on key points for dialogue before communicating with NRAs
- ✓ Two papers published, increasing awareness of challenges and solutions
- ✓ Supporting regulatory open discussions at stakeholder meetings, as for example:
  - **AVAREF, ICDRA, ASEAN, PANDHR, CoRE**
- ✓ Study on changes/variations to improve vaccines' access
- ✓ 3Rs: innovative assays to reduce animal use



<https://www.ncbi.nlm.nih.gov/pubmed/29724510>

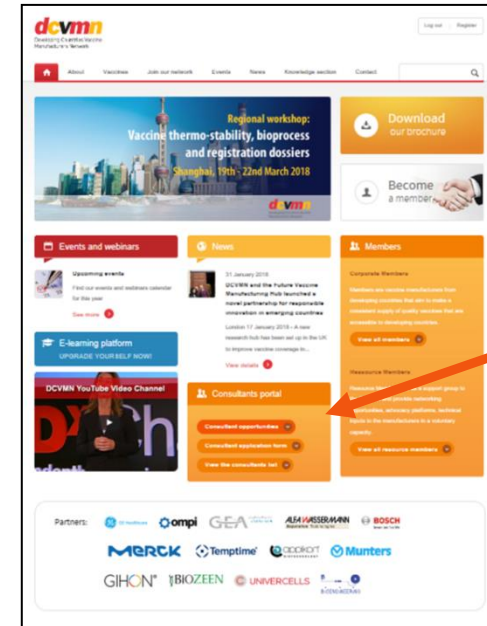


In press



## 4. Access to International Experts

- **DCVMN's Consultants Portal at [www.dcvmn.org](http://www.dcvmn.org)**
- Consultants register themselves in the DCVMN database
  - Centralized pool of expertise
  - Transparency on qualifications
  - Consultants based in 22 countries
  - Declared availability to DCVMN and to Members
  - Not working for other manufacturers and “moonlighting”
- > 100 registered consultants; ca. 50% already “engaged” by DCVMN



2 funding calls – Oct 2018 and Feb 2019 (up to \$50,000) for consultancy support for developing country members of DCVMN.

Imperial College  
London

FVMR Hub awarded \$90,000 to two such members (one manufacturer in China and another in India).

Next call in ~Oct 2019.



- How to ensure calls meet needs of manufacturers
- How to improve the quality of the application
- How to grow enduring partnerships

## 5. Engage members on innovative technologies adoption

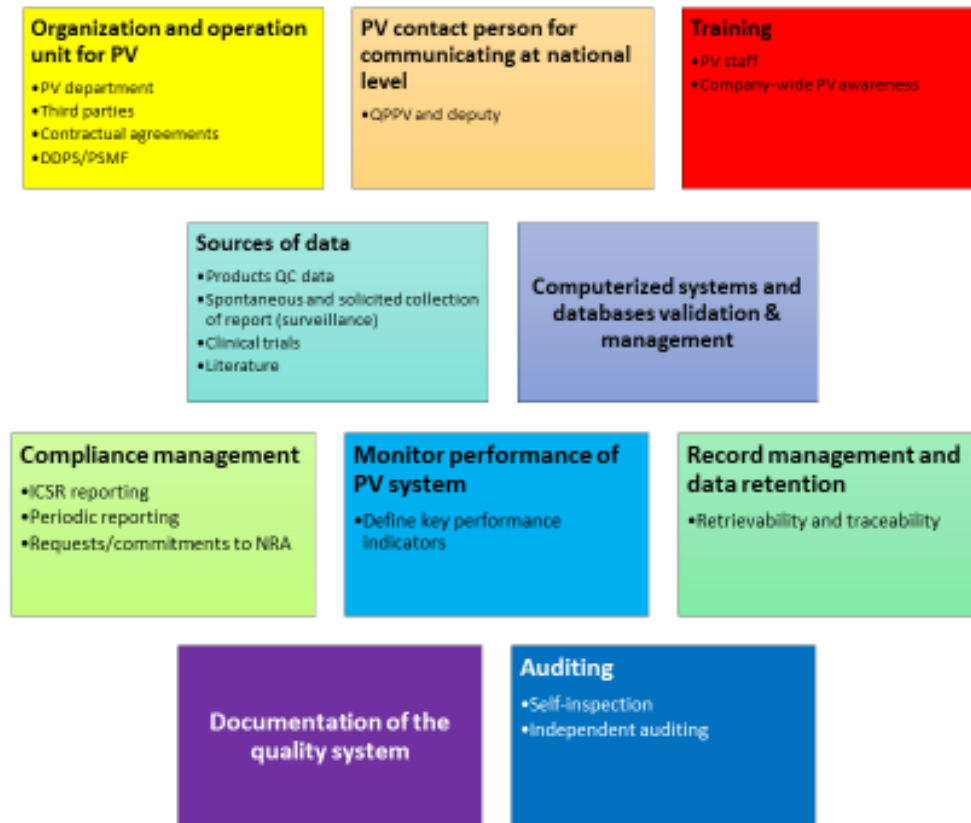


30<sup>th</sup> October 2018, AGM,  
Bill Gates: “looking forward to the partnerships  
we can have over the next decade”

[https://www.dcvmn.org/IMG/pdf/bill\\_gates\\_kunming\\_video\\_news.pdf](https://www.dcvmn.org/IMG/pdf/bill_gates_kunming_video_news.pdf)

# 6. Pharmacovigilance (PV) to improving vaccines safety monitoring

## Building Blocks of Efficient Quality Systems for Pharmacovigilance\*

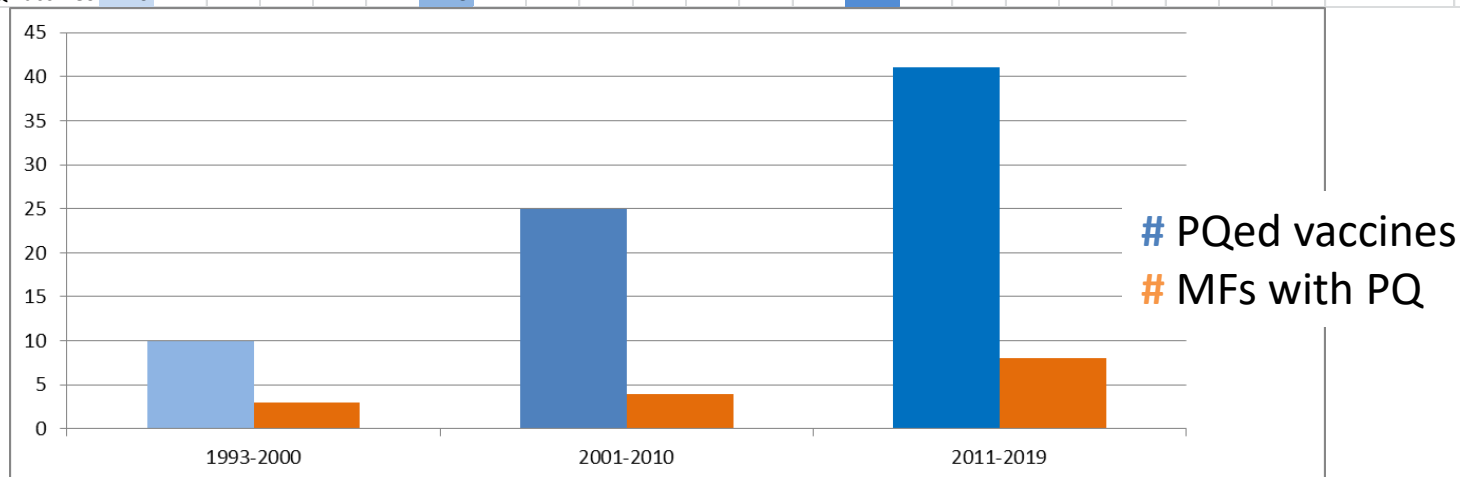


\*Courtesy of O. Menang, PATH

# Number of DCVMs PQed vaccines over 25 years:

## DCVMN works

Manufacturer/Year	1993	1995	1996	1997	1999	2000	2001	2003	2004	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	PQ vaccines	Manufacturer
Bharat/India																			1		2	1		4	Bharat
BioE/India													1		1	2	1		2		1		1	9	BioE
BioM/Brazil							1				1													2	BioM
Cadila HC																							1	1	
CNBG/China																	1				1			2	CNBG
EuBiologics/Korea																			1		1			2	EuBiologics
GreenCross/Korea														1	1	1				1	1			5	GreenCross
Green Signal/India																			1					1	GreenSignal
Haffkine/India										1			1	1										3	Haffkine
LG Chem/Korea			1														1			1				3	LGChem
Panacea/India																		1				1		2	Panacea
Biofarma/Indonesia				2	2		1	1	2	1			1	1	1			1	1					14	Biofarma
Serum Institute/India	1	3				1		2	1	2		1		3		1	1	2	1	1		2		22	Serum Institute o
Sinovac/China																					1			1	Sinovac
SK Biosciences																							1	1	
<b>Total</b>	<b>15</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>3</b>	<b>4</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>6</b>	<b>3</b>	<b>5</b>	<b>4</b>	<b>5</b>	<b>5</b>	<b>4</b>	<b>7</b>	<b>6</b>	<b>2</b>	<b>72</b>	from ca. 146 Total
# PQ vaccines	10						23								41										



# Memberships and Strong Partnerships towards building healthy countries



Credit: <http://www.vibincblog.com/?tag=partnership>

“Coming together is a beginning;  
keeping together is progress;  
working together is success.”



# 3Rs

- **Reliable:**
  - able to be trusted; consistently good in quality or performance: «yes means yes, no means no» attitude
- **Responsive:**
  - responding readily and with interest or enthusiasm: «answer to queries, emails, reports, etc.» attitude
- **Responsible:**
  - be answerable for one's actions; having control over or accountable for something, as part of one's job/ role.
  - “Yes, I do” , “yes, I can” , “yes, I will” attitude

# DCVMN Collaborating organizations and Partners

Imperial College  
London

BILL & MELINDA  
GATES foundation

Temptime®

GE Healthcare



ROMMELAG

MERCK



GEA

BIOENGINEERING

SG Stevanato Group

BIOZEEN



intravacc



GIHON

Tofflon



sartorius

UNIVERCELLS

Center for Vaccine  
Ethics and Policy  
UPenn | Wistar Institute | CHOP



PATH

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*Individually we are one drop, together we are an ocean*

*Ryunosuke Satoro*

**DCVMN International**

**[www.dcvmn.org](http://www.dcvmn.org)**