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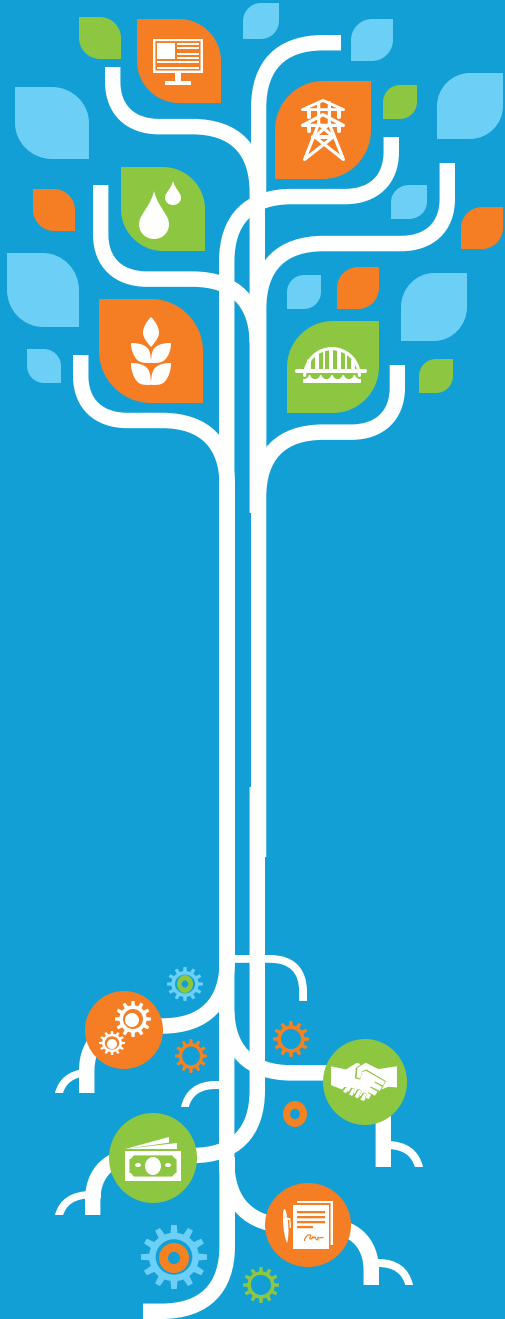
ADB

Supporting the immunization and vaccine manufacturing in Asia and the Pacific

11 October 2022

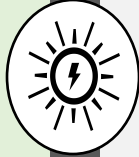
Rui Liu
Health Specialist
Sustainable Development & Climate Change Department

BUSINESS
OPPORTUNITIES



COVID-19 REVEALED STRENGTHS AND VULNERABILITIES

1



Outstanding success of almost 70% full COVID-19 vaccination despite difficulties in stable supply of high quality vaccines

2



Success obtained by multiple inter-connected agencies working together (vaccine surveillance, cold chain, human resources, communications)

3



Years of prior preparation came together in time of crisis. However, future health threats will require more complex tasks

4



Areas that exposed vulnerabilities - non-pharmaceutical interventions, lack of equipment and supplies such as oxygen, PPE kits, ventilators, hospital beds, human resources etc.

Resilience is everybody's concern, but nobody's core output

COVID-19 REVEALED KEY FOCUS AREAS

Early warning system

Through strengthened MIS surveillance, laboratory systems, and data accuracy and sharing

Surge capacity including vaccination

Early warning system, vaccines, diagnostics, therapeutics, and strong national regulator

Whole of society approach

Essential for health system resilience with a special focus on digital ecosystem

Primary healthcare and HRH

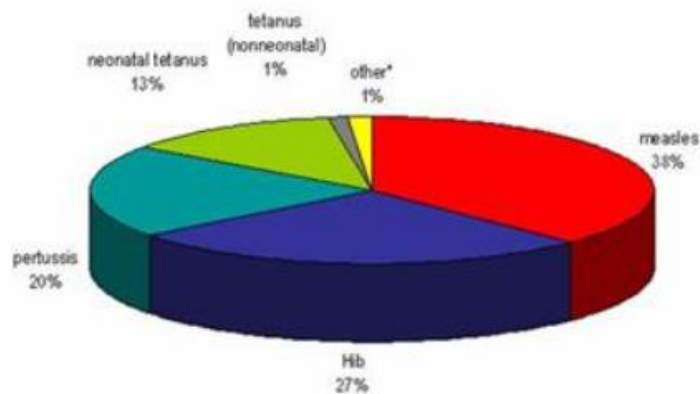
Strengthened alongside emerging changes in demographics and diseases

Future threats

Including climate change, anti-microbial resistance, NCDs, elderly care, mental wellbeing etc.

Immunization contributes to 14 of 17 SDGs

- Between 2010 and 2017, the mortality rate of children under 5 years of age decreased by **24%**, due in large part to immunization.
- In countries that have introduced the vaccine against human papillomavirus (HPV), after 5–8 years, cancer causing HPV prevalence was reduced by **83%** among girls aged 13–19.
- The widespread use of the pneumococcal conjugate vaccine (PCV) could reduce the number of days on antibiotics for pneumonia in children under 5 years by 47%, equivalent to **11.4 million days** on antibiotics per year.
- Immunization against measles in 94 low- and middle-income countries returned an estimated **US\$ 76.5** for every US\$ 1 invested in vaccination.
- Vaccines will help keep an estimated **24 million** people from falling into poverty by 2030.



1.4 million vaccine preventable deaths under 5 years old, accounting for 14% of annual deaths in this age group

* other – polio, diphtheria, yellow fever



Immunization plays a key role in **eliminating poverty**, by reducing treatment costs and increasing longer-term productivity by averting losses due to disability and death.



Immunization promotes a **healthy and productive workforce**, which contributes to the economy.



Immunization and **nutrition** go hand in hand. Malnourished individuals, especially children, are more likely to die from infectious diseases such as diarrhoea, measles and pneumonia.



Vaccine manufacture contributes to national industrial **infrastructure** in low- and middle-income countries.



Vaccination is one of the most cost-effective ways of saving lives and promoting good **health and well-being**.



Immunization prevents diseases that affect **the most marginalized groups**, especially those in poor urban or remote rural settings and in areas of conflict.



Immunization increases **educational attainment**, as it improves long-term cognitive development. Children who are immunized tend to attain more years of schooling and score higher in cognitive tests than those who are unvaccinated.



Immunization protects urban public health and interrupts disease transmission, ensuring **sustainable cities and communities**.



Removal of gender-related barriers to vaccination contributes to **gender equality**, as it supports women's full participation and equal opportunities for accessing health services.



Immunization is critical to building people's resilience to and mitigating the risk of disease outbreaks linked to **climate change**, such as yellow fever, malaria, meningitis and cholera.



When vaccination is complementary to **clean water, sanitation and hygiene**, it prevents diarrhoeal diseases, which are the leading cause of child mortality in low-income countries.



Effective, safe, people-centred health systems are the backbone of social institutions, and vaccination is often the regular point of contact of the population with the system.



Immunization logistics increasingly involve use of cleaner, more sustainable techniques based on solar and other **renewable sources of energy**.



Immunization programmes broaden **partnerships** and multisectoral approaches, ensuring that civil society, communities and the private sector work together towards common goals.

Global immunization goals and targets by 2030 (1)

Disease-specific goal or initiative	Targets
Polio eradication (GVAP, Polio Endgame Strategy 2019–2023)^a	Interrupt transmission of all wild poliovirus by 2020. Stop circulating vaccine-derived poliovirus outbreaks within 120 days of detection. Certify eradication by 2023.
Neonatal tetanus elimination (GVAP)	Eliminate neonatal tetanus in the remaining 40 countries by 2015.
Measles and rubella elimination (GVAP, Global Measles and Rubella Strategic Plan 2012–2020)	Eliminate measles in at least five WHO regions by 2020. Eliminate rubella in at least five WHO regions by 2020.
Cholera control (Ending Cholera – A Global Roadmap to 2030)	Reduce cholera deaths by 90% by 2030.

Global immunization goals and targets by 2030 (2)

Disease-specific goal or initiative	Targets
Elimination of viral hepatitis as a major public health threat (Global Health Sector Strategy on Viral Hepatitis 2016–2021)	<p>Reduce new cases of chronic viral hepatitis B infections by 95% by 2030 (equivalent to 0.1% prevalence for HBsAg among children).</p> <p>Reduce viral hepatitis B deaths by 65% by 2030.</p>
Control of vector-borne diseases (including Japanese encephalitis) (Global Vector Control Response 2017–2030)	<p>Reduce mortality due to vector-borne diseases by at least 75% by 2030.</p> <p>Reduce case incidence due to vector-borne diseases by at least 60% by 2030.</p> <p>Prevent epidemics of vector-borne diseases in all countries by 2030.</p>
Elimination of yellow fever epidemics (Eliminate Yellow Fever Epidemics)	<p>Reduce yellow fever outbreaks to zero by 2026.</p>
Elimination of meningitis epidemics and reduction of cases and deaths (Global Roadmap to Defeat Meningitis)	<p>Eliminate meningitis epidemics by 2030.^b</p> <p>Reduce the numbers of cases and deaths from vaccine-preventable bacterial meningitis by 2030.^c</p> <p>Reduce disability and improve quality of life after meningitis due to any cause by 2030.</p>
Reduction of seasonal influenza burden (Global Influenza Strategy 2019–2030)	<p>No disease-specific targets.</p>
Zero deaths from dog-mediated rabies by 2030 (Zero by 30: The Global Strategic Plan)	<p>Reduce the number of deaths from dog-mediated rabies to zero by 2030.</p>

Seven strategic priorities for immunization agenda 2030

Fundamental:

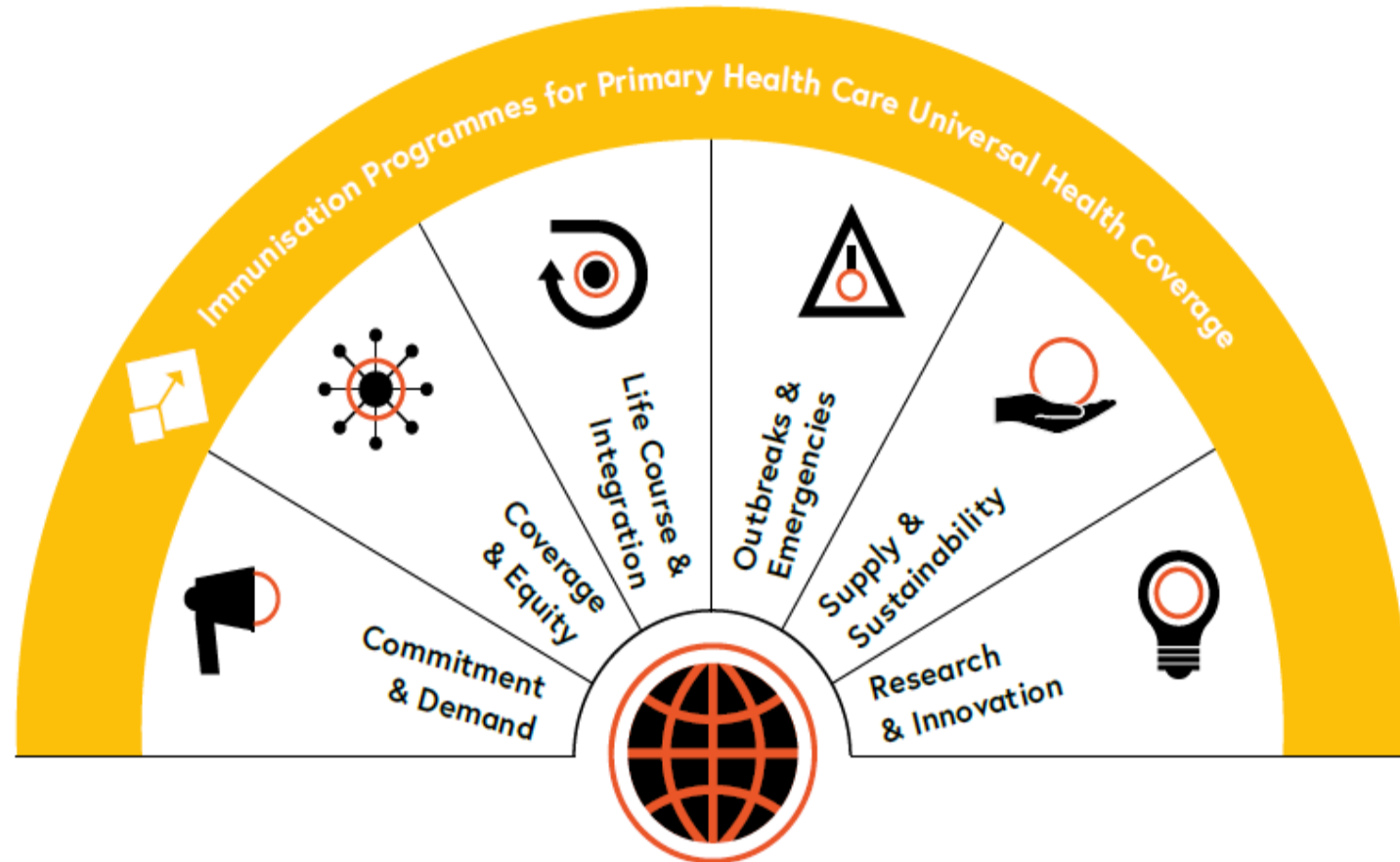
- An integral part of primary health care (UHC)
- Community demand

Delivery of immunization:

- Coverage and equity
- Life-course and integration
- Outbreaks and emergencies

Enabling environments:

- Supply and sustainability
- Research and Innovation



Four core principles for support immunization programs



People-centred

Responding to populations needs.

The design, management and delivery of immunization services should be shaped by and responsive to the needs of individuals and communities, including addressing barriers to access to immunization services due to age, location, social and cultural norms and gender-related factors.



Partnership-based

Aligning efforts to maximize impact.

Immunization partners should align and coordinate their actions to increase efficiency, build on complementarity and involve sectors beyond immunization for mutual benefit.



Data-guided

Promoting evidence-based decision-making.

High-quality, "fit-for-purpose" data will be used to track progress, improve programme performance and form the basis of decision-making at all levels.



Country-owned

Driving progress from the bottom up.

Countries should establish targets that represent the local context and should be held accountable for achieving them.

- Programs to be designed and tailored to the **needs and social, cultural preferences** of people and communities;
- **National strategies and plans** for sustainability
- Public-private **partnership**, including civil society organizations
- **Data, evidence** and best practice to guide programs

Immunization is a cost-effective intervention with health and economic impact

\$1 Spent on immunization

\$21 Saved in healthcare costs

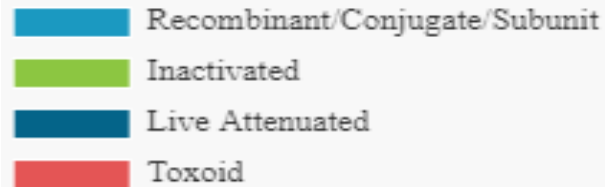
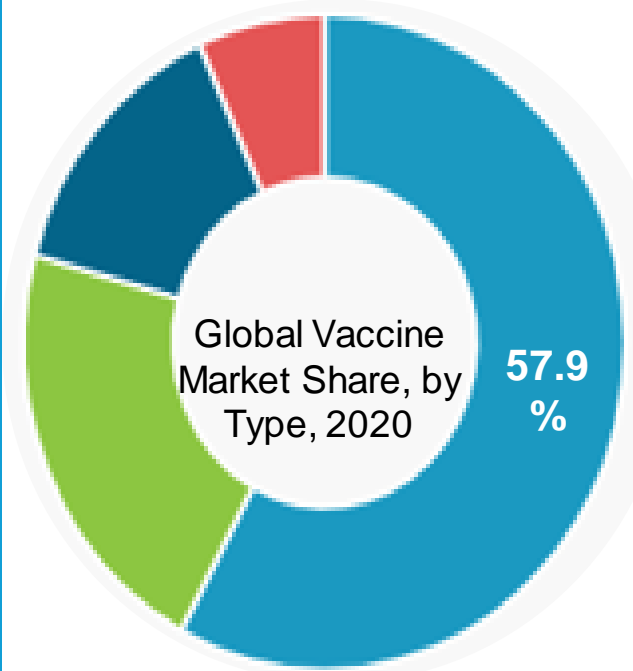
\$44 Economic and social benefits

\$54 Return on investment



<https://www.gavi.org/programmes-impact/our-impact/facts-and-figures>

Global Vaccine Market Overview



www.fortunebusinessinsights.com

1

Global vaccine market projected to grow from \$61.04 billion in 2021 to \$125.49 billion in 2028 at a CAGR of 10.8%

2

Growing supply for products by UNICEF, WHO, PAHO, GAVI to Aid Immunization Process

3

High vaccine cost may limit vaccine adoption in low-income countries

4

Effectiveness of the recombinant/conjugate/subunit segment to generate the highest market value

5

Growing demand for bacterial types to dominate the market

6

Majority of the market share is attributed to an increase in pediatric injection doses.

Rationale for ADB to support vaccine manufacturing

1

Countries in developing Asia (INO, BAN, etc.) on track to graduate from the UN's Least Developed Countries (LDC) - GAVI subsidy for vaccines and immunization being phased out

2

High demand for vaccines and ensuring bio-security (for example, the birth cohort of around 3 million, lifecycle approach, and travel vaccines in Bangladesh)

3

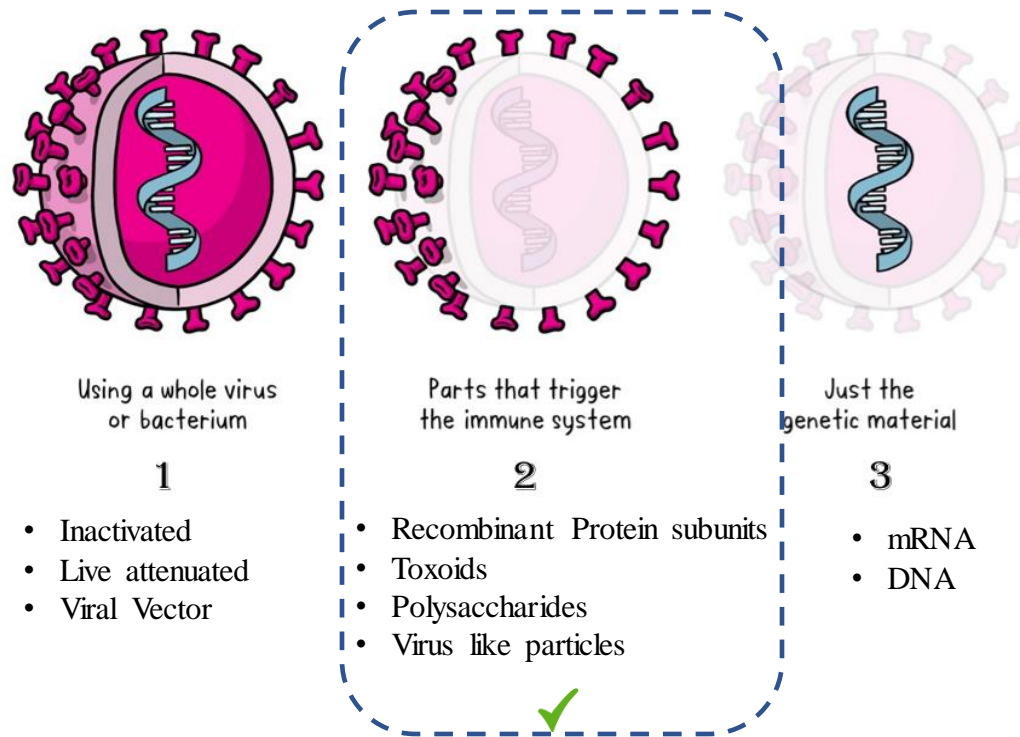
Demand Side Management - High Success in Vaccination Coverage

4

Alarming Anti-Microbial Resistance issues

Vaccine Manufacturing and Development Approaches: Lessons from Indonesia

There are three main approaches to making a vaccine:



1. Capex and opex can be optimised, as multiple vaccines can be manufactured in the same facility on a campaign basis
2. Established regulatory procedures
3. Many of the vaccines currently in the EPI can be manufactured in the same facility.
4. Proven technology
5. Less complex as compared to the other two approaches
6. Know-how relatively easily available
7. Raw-material, required skilled human resource available
8. For all the targeted vaccines, the maximum biosafety level (BSL) required is 2.
9. If needed, the recombinant subunit based Covid-19 vaccine also can be manufactured in the same facility

Possible scenarios for National Immunization Program: lessons from Indonesia

BASELINE SCENARIO

Current NIP

Sr. No.	National Immunization Program
1	Bacille Calmette-Guerin vaccine (BCG)*
2	DTP-Hib-HepB (Pentavalent)
3	Measles and rubella vaccine (MR)*
4	Pneumococcal conjugate Vaccine (PCV 10)
5	Inactivated Polio Vaccine (IPV)
6	Oral Polio Vaccine (OPV)
7	Tetanus toxoid (TT)

- Covers 4 out of 7 vaccines
- 70% of total volume
- 90% of total value

SCENARIO A

BS + HPV + RVV

Sr. No.	National Immunization Program + HPV and RVV
1	BCG
2	Pentavalent vaccine
3	MR
4	PCV 10
5	IPV
6	OPV
7	TT
8	Human papillomavirus vaccines (HPV)
9	Rotavirus vaccine (RVV)

- Covers 5 out of 9 vaccines
- 67% of total volume
- 86% of total value

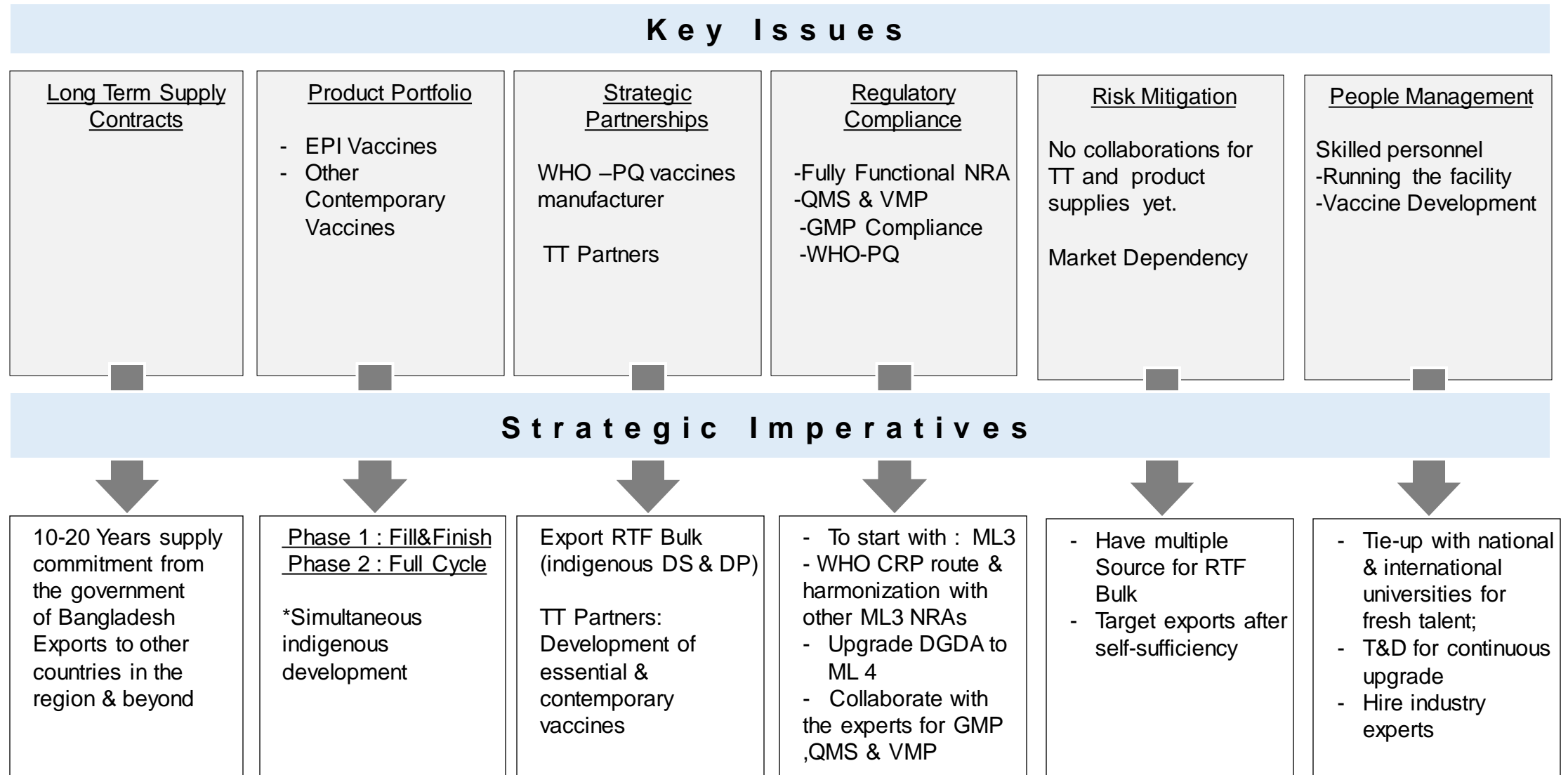
SCENARIO B

SA + JE + TCV

Sr. No.	National Immunization Program + JE & TCV
1	BCG
2	Pentavalent vaccine
3	MR
4	PCV 10
5	IPV
6	OPV
7	TT
8	HPV
9	RVV
10	Japanese encephalitis vaccine (JE)
11	Typhoid conjugate vaccine (TCV)

- Covers 7 out of 11 vaccines
- 67% of total volume
- 84% of total value

Bottlenecks and Mitigation Measures



SWOT Analysis

STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> Public sector entity – Support from the Govt. agencies Prior experience of pharma manufacturing & now venturing into manufacturing of sterile products The existing human resource pool can be upgraded for vaccine manufacturing with appropriate T&D 	<ul style="list-style-type: none"> Funding – <i>Through MDBs and other funding agencies</i> Perception – <i>Commitment for WHO accepted quality standards</i> NRA & NCL – <i>Bring in expertise through partner countries</i> EDCL Protocol – <i>Committed to making it prompt, decisive and less bureaucratic</i> Technical Talent – <i>Continuous T&D programs at organizational level. Tie-ups with academic institutions.</i> Full Green Field – <i>Strategic advisory support to comply with cGMP</i> 	<ul style="list-style-type: none"> GAVI Graduating – Indigenous manufacturing of vaccines Sizeable birth cohort and suitable demography->Volumes->Viability Most of the contemporary vaccines in EPI 1st public sector entity – Manufacturing facility to manufacture essential and contemporary vaccines for Bangladesh Along with essential vaccines, new vaccines for regional diseases can be developed Supply to the region and beyond. 	<ul style="list-style-type: none"> Price Competition and private company from DCVM – <i>Partner with DCVMN members</i> Bureaucracy & change of Govt Policy – <i>Broad based advocacy groups. Objective and commitment for better health for people of Bangladesh and the region.</i> Re-emerging & newly emerging diseases – <i>Provision for R&D and partnership in the project plan supported by manufacturing infrastructure</i> Advances in Technology (Newer Technologies) – <i>Collaboration with international research institutes, universities and setting up of National Centre of Excellence.</i>

*** Green highlights are mitigation measures**

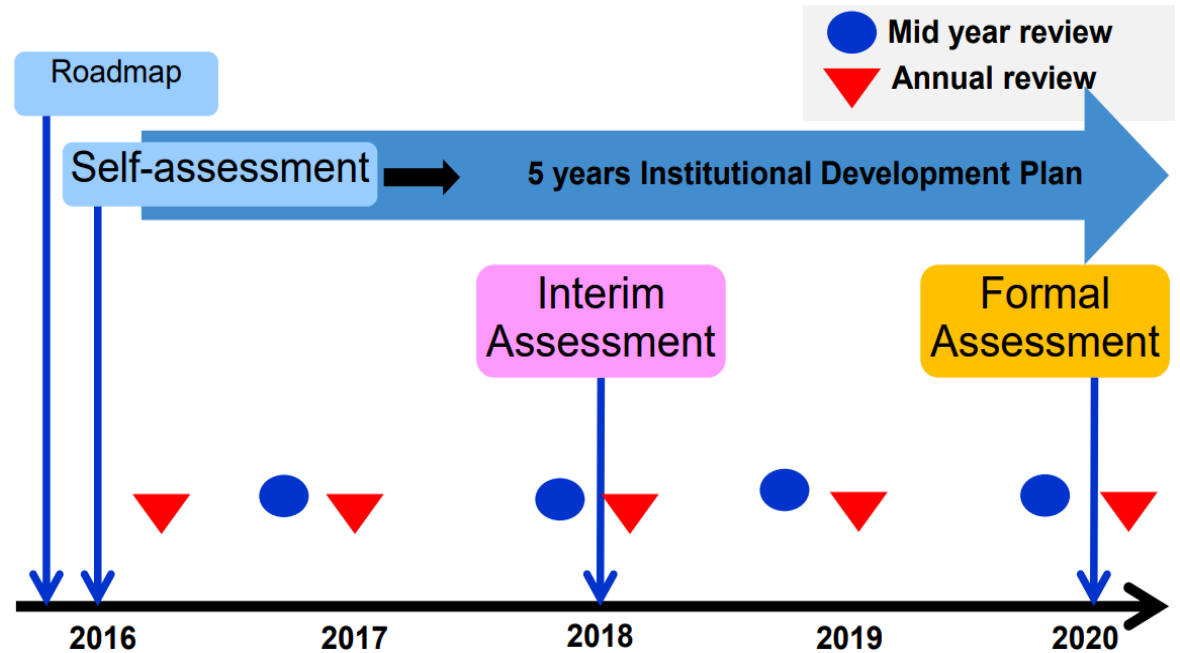
Regulatory Status and Roadmap



01	National Regulatory System (RS)
02	Registration and Marketing Authorization (MA) ..
03	Vigilance (VI)
04	Market Surveillance and Control (MC).....
05	Licensing Establishments (LI)
06	Regulatory Inspection (RI).....
07	Laboratory Testing (LT)
08	Clinical Trials Oversight (CT).....
09	NRA Lot Release (LR).....

9 Parameters of Global Benchmarking Tool

Bangladesh road map (2016-2020)



Self-assessment has been completed by Bangladesh NRA

Indonesia is at Maturity Level 3, while Bangladesh is currently at Maturity Level 2 as per the Self Assessment

List of WHO Pre-Qualified Vaccine Manufacturers

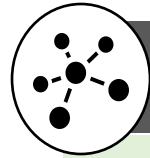
Sr.No.	List of Vaccines	Presentation	Formulation	Manufacturers (WHO PQ)
1	TT	MDV (10 dose; 20 dose)	Fully Liquid	1.Serum Institute of India (India) 2.Biological E. Limited (India) 3.PT Biopharma (Indonesia) 4.BB- NCIPD Ltd. (Bul Bio-National Center of Infectious and Parasitic Diseases Ltd.) (Bulgaria) 5.Sanofi Pasteur (France)
2	Recombinant Hepatitis B Vaccine (Pead)	SDV (1 dose)	Fully Liquid	1.LG Lifesciences (South Korea) 2.Biological E (India - In Process WHO PQ)
3	Pentavalent Vaccine (DTwP-Hib-Hep B)	MDV (10 dose)	Fully Liquid	1.Serum Institute of India (India) 2.Biological E. Limited (India) 3.LG Chem (South Korea) 4.PT Biofarma (South Korea) 5.Panacea Biotec (India)
4	Inactivated Poliomyelitis Vaccine(Sabin IPV)	MDV (5 dose)	Fully Liquid	1.L G Chem (South Korea) 2.Sinovac Biotec Co. Ltd. (China) 3.Beijing Institute of Biological Products Co., Ltd. (China)
	Inactivated Poliomyelitis Vaccine(Salk IPV)	MDV (5 dose)	Fully Liquid	4.Sanofi Pasteur (France) 5.AJ Vaccines A/S (Denmark)
5	Human papillomavirus (bHPV) Vaccine	SDV; MDV (2dose)	Fully Liquid	1.Serum Institute of India (In Process WHO PQ) 2.Xiamen Innovax Biotech Co. Ltd. (China) 3.GlaxoSmithKline Biologicals (UK)
6	Japanese Encephalitis Vaccine (Inactivated) (3µg Pediatric)	SDV; MDV (5 Dose)	Fully Liquid	1.Biological E. Limited (India)
	Japanese Encephalitis Vaccine (Inactivated) 6µg			
7	Pneumococcal Conjugate Vaccine	SDV, MDV (5 Dose)	Fully Liquid	Serum Institute of India (WHO PQ) (PCV-10) (India) Pfizer Ltd. (PCV-13) (USA) GlaxoSmithKline Biologicals (PCV-10) (UK)
a. Manufacturers have been selected based on the WHO pre-qualification and availability of required product presentation.				
b.Exhaustive list of qualifying manufacturers can be accessed on product and case basis.				
c. SDV: Single Dose Vial; MDV: Muti-dose Vial				

Regulatory Upgradation Way Forward – Investment opportunities



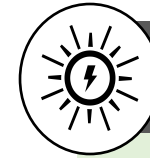
LABORATORY COMPLEX

1. Establishing testing facilities of vaccine, biologics, biosimilar drugs, biotech derived drugs and medicine, API, traditional medicine, medical device, medical gas, diagnostic reagents etc.
2. Equipment & HR
3. Operational cost



POST MARKETING SURVEILLANCE

1. Logistic support like transport infrastructure, storage and technical capability of cold chain management for vaccine sampling
2. Construction of office building up to district level (Land to be requested for allotment by Government)
3. IT infrastructure
4. Operational cost



CAPACITY BUILDING

1. Establishment of training center
2. Providing training (short, medium- & long-term including university courses) at international level
3. Collaboration programs with other ML 3 NRAs
4. IT support

Regulatory Upgradation Way Forward (example of Bangladesh)

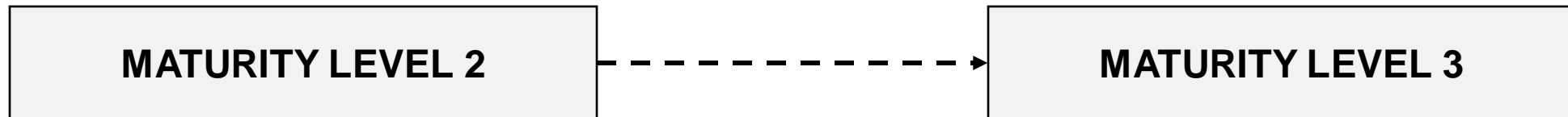
Sr.No.	Global Benchmarking Tool Parameters for Assessing Maturity Level Status	Abbreviation	Sub-indicators % implemented	Current (ML) Status
1	NRA Lot Release	LR	85	1
2	Laboratory Testing	LT	68	2
3	Registration and Marketing Authorization	MA	81	2
4	Licensing Establishment	LI	80	1
5	Market Surveillance and Control	MC	81	1
6	Vigilance	VI	88	1
7	Clinical Trials Oversight	CT	73	1
8	Regulatory Inspection	RI	72	1
9	National Regulatory System	RS	67	1

Strengthening of DGDA will enable Bangladesh to seek recognition as a WHO Listed Authority (WLA), eligibility for WHO prequalification, and export of vaccines.

Regulatory Status and Roadmap

Total No. of Recommendations	Total No. of CAPA	No. of CAPA upto ML 3	No. of CAPA in ML 4	Total No. of CAPA deadline within Dec'2021	CAPA already closed (ML3+ML4)
68	38	35	03	28	21+01

Recent Status : 2022



Maturity level 3 / functional status is a prerequisite for WHO prequalification of locally manufactured vaccines

CAPA: Corrective and preventive actions. ML: Maturity Level

Engaging the private sector and health sector reform

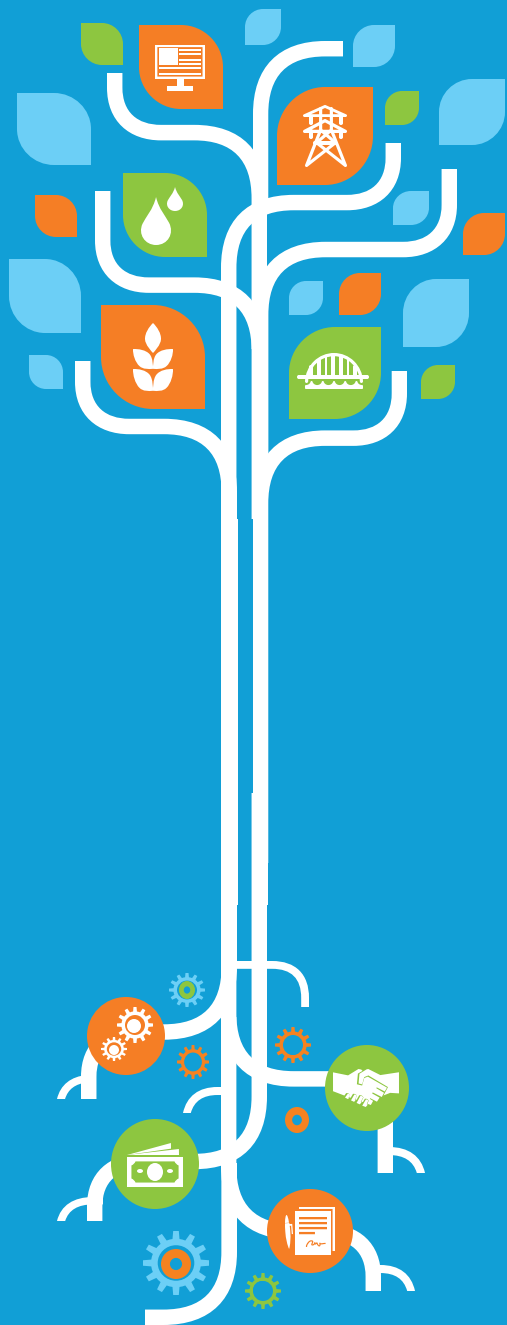
- Some countries have **significant private health** markets. In Indonesia **49%** of births were with a private provider, **44%** in Pakistan (2017)
 - Yet stewardship and regulation of the private sector remains weak²
- For all countries with **ongoing structural reforms**, using evidence to adapt strategies and engage the private sector will be key; for example:
 - **India**: hospital care under PM-JAY and impact on reducing OOP; reorganizing urban PHC
 - **Philippines**: implementing financial and provider integration per the UHC Act
- Asia Pacific countries will need budgetary space to pursue expansion and deepening of social insurance systems (i.e., true reach, higher quality)
 - **Thailand**-type, geared to combat NCDs, higher quality, more expensive, high subsidy share
 - **Indonesia** is beginning to head in Thailand's direction, but with constrained budgetary space
 - Or **Viet Nam**: 88%+ coverage of SHI, high subsidy component, and not yet supplying high breadth and depth of care, while facing financial unsustainability



Looking Outward: Health Pipeline, 2022

Values in US\$ millions

Country	Project	ADB
Central and West Asia (\$70 million)		
Kyrgyz Republic	Strengthening Diagnostic and Reference Laboratory Capacity Project	20
Pakistan	KP Health Systems Strengthening	50
South Asia (\$250 million)		
India	Supporting Health Systems Development Program (PM-ASBY) (Subprogram 1)	250
Southeast Asia (\$300 million)		
Indonesia	Supporting Essential Health Actions and Transformation Project/Program	300
Total Loans and Grants, 2022		620



THANK YOU!

Rui Liu

Health Specialist, SDSC-HEA

ruiliu@adb.org