Landscape assessment and Policy Recommendations

Scaling nucleic acid-based biopharmaceutical technologies in Asia-Pacific

Key highlights

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Speakers

RAGINI AHLUWALIA

**Global Health Lead – Asia Pacific, Senior Manager,
Accenture Development Partnerships**

VARUN SRIVASTAVA

**Global Health Manager,
Accenture Development Partnerships**

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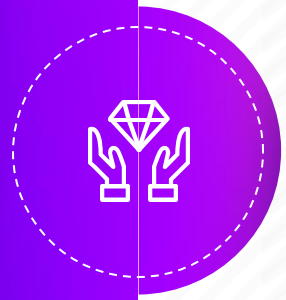


01

Nucleic acid market landscape assessment for the Asia and the Pacific region

- Background and context
- Technology overview
- Market sizing overview
- Final recommendations

02

Capacity building policy briefs for Bangladesh

- Background and context
- Current situation and recommendations for:
  - Creating an enabling environment for vaccine manufacturing
  - Clinical trial ecosystem strengthening
  - Regulatory system strengthening

01: NUCLEIC ACID MARKET LANDSCAPE ASSESSMENT

Project background and context

Accenture was contracted by ADB to outline the market landscape and potential of nucleic acid-based technologies, and to develop policy briefs related to vaccine manufacturing ecosystem strengthening

Key Objectives

Developed **a landscape & market assessment report** detailing the potential of nucleic acid-based biopharmaceutical technologies, focusing on the **Asia and the Pacific region**

Developed **an estimate of future value of demand** for nucleic acid-based technologies

Provided **support to Bangladesh DMC on policy and capacity development** for strengthening its biopharmaceutical manufacturing sector

Accenture undertook a comprehensive secondary research coupled with key stakeholder consultations to inform the market assessment and policy briefs

1. RAPID REVIEW

PIPELINE IDENTIFICATION → FILTERING → INDICATION AND PHASE MAPPING → RISK ADJUSTED LAUNCH ESTIMATES → PRIORITIZATION

Looked at the maturity and potential for impact for 5 nucleic acid technologies to shortlist 3

2. DEEP DIVES

1 TECHNOLOGY OVERVIEW → 2 CURRENT STATE OF THE TECHNOLOGY → 3 MARKET DYNAMICS → 4 OUTLOOK

Conducted a thorough landscaping and market assessment for 3 priority technologies

3. MARKET SIZING

Address-able pop-ulation × Market share × Annual cost of therapy = Country market size

Estimated market sizes for each sub-category at a country level

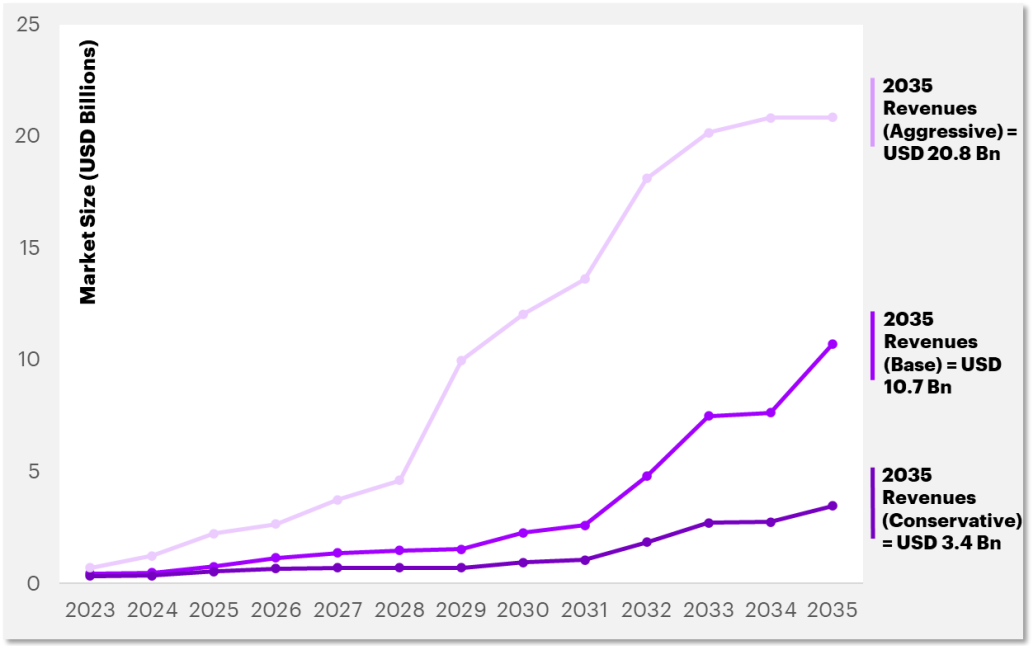
Five emerging nucleic acid-based technologies were assessed to rapidly prioritize them for further deep dives

PRIORITY

	Technology Overview		Number of clinical trials by technology class across 2005-22[1,2]			
	Description & Mechanism of Action	Therapy Areas	2005-09	2010-14	2015-19	2020-
Antisense Oligonucleotides (ASOs)	*Short single stranded oligonucleotides which inhibit gene expression by hybridizing to the coding sequences of a specific mRNA targets[1]*	• CVD • Oncology • Infectious Diseases • Nervous System	1	1	13	47
DNA Plasmids	*Base for DNA vaccines and gene therapies, works by acting as a vector for introducing appropriate DNA sequences to produce required responses[2]*	• Infectious Diseases • Oncology	5	20	17	16
siRNA	*Class of nucleic acid-based drugs able to block gene expression by interaction with mRNA before its translation[3]*	• CVD • Oncology • Dermatology • Infectious Diseases			23	52
mRNA	*Use lab created mRNA to teach our cells how to make a protein—or even just a piece of a protein—which triggers an immune response[4]*	• Infectious Diseases (Vaccines) • Oncology • Digestive/Metabolic Disorders		2	32	164
Aptamers	*Aptamers are single-stranded DNA or RNA molecules that bind to protein targets , inhibiting protein–protein interactions [5]*	• Ophthalmology • Oncology	5	4	3	2

The market value of nucleic-acid technologies was estimated to reach USD 10.7 Bn revenues by 2035 in the Asia and the Pacific region

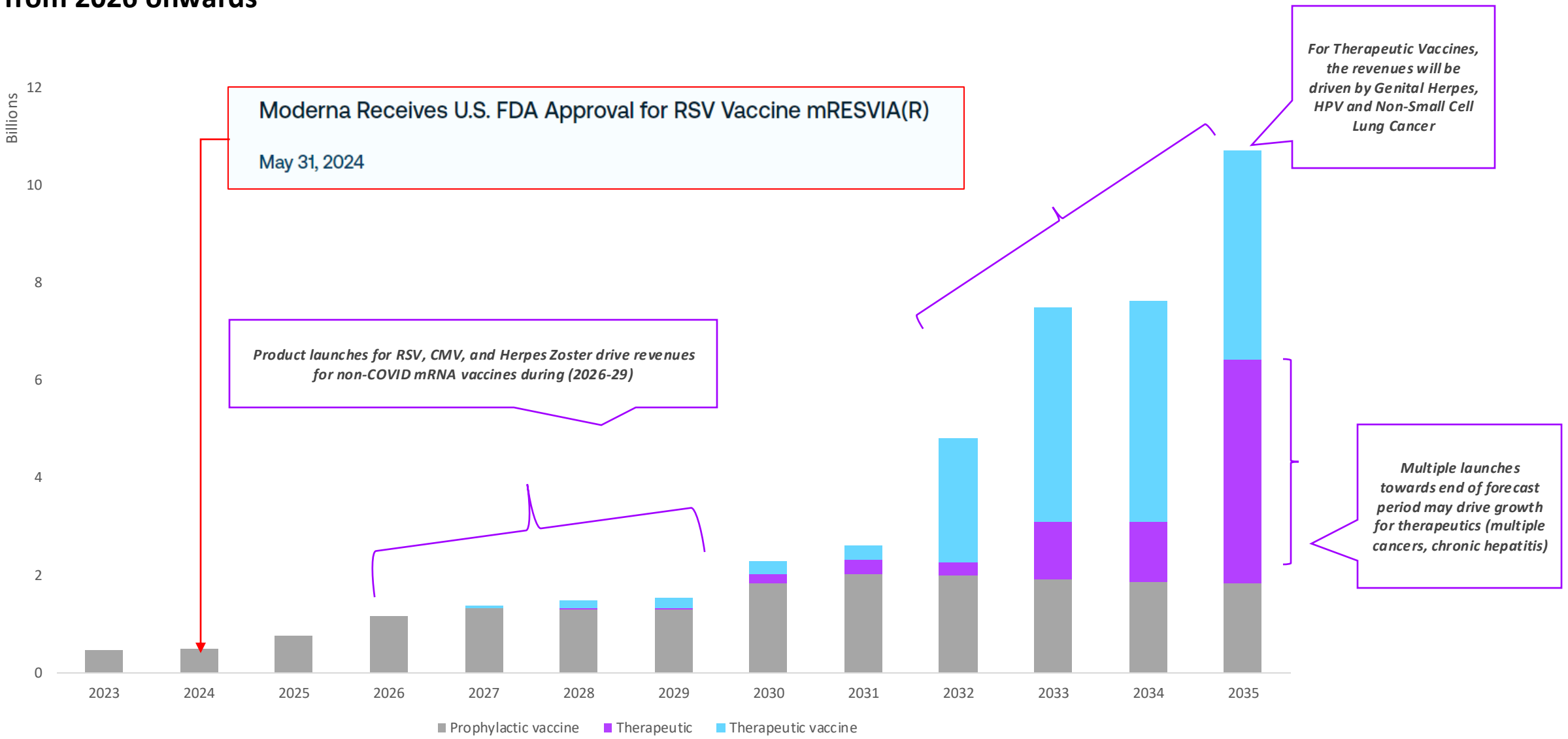
- Out of five nucleic acid-based technologies studied, **mRNA, DNA plasmids and siRNA show the most potential in terms of public health impact, indication coverage and #products in pipeline**



Market sizing (Asia-Pacific) (Base case scenario)			
	mRNA	DNA	siRNA
Expected revenue in Asia and the Pacific 2035 (in USD)	$ 6.4 Billion	$ 0.49 Billion	$ 3.8 Billion
Compound Annual Growth Rate (2024-2035)	25%	83%	65%

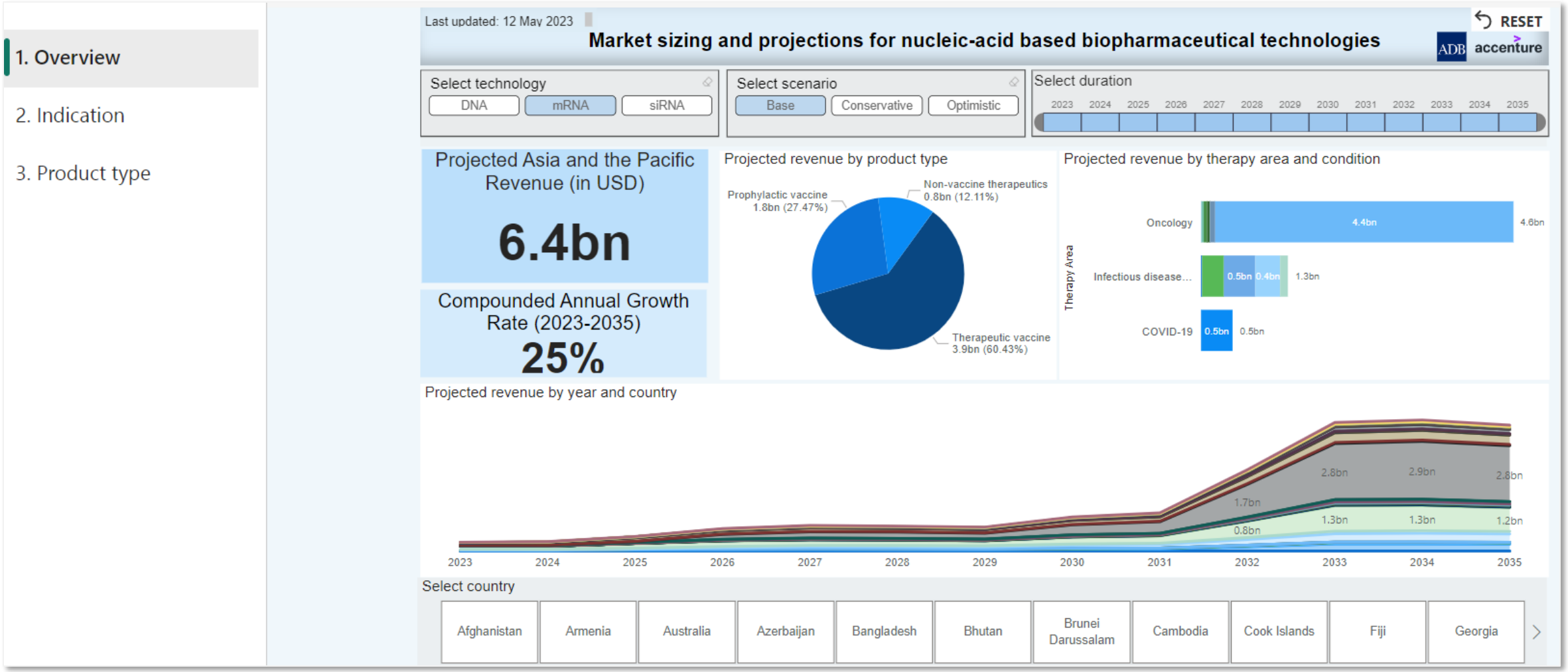
- While **modern vaccine platforms offer greater flexibility**, **traditional vaccine technologies will continue to form the predominant share of the global vaccine demand** for years to come. Thus, countries must make informed decisions on investments in specific platforms for domestic manufacturing considering their **current capabilities and future requirements**.

Product launches for non-COVID diseases were forecasted to supplement decreasing COVID-19 revenues from 2026 onwards



Market size dashboard

An interactive tool was developed for ADB to visualize the results from the market sizing analysis for nucleic acid-based technologies in the Asia and the Pacific region



Final recommendations

Based on the market sizing analysis, the chosen nucleic acid-based technologies show promise and potential for health security, particularly in the medium and long term

	Short-term	Medium-term	Long-term
mRNA technology	• The focus is currently on COVID-19	• mRNA vaccines could be used to prevent other infectious diseases such as influenza and Zika virus	• The focus is expected to shift towards stimulating the immune system to target cancer cells
DNA plasmids technology	• The focus is currently on COVID-19	• DNA plasmid technology is expected to be utilized for prevention of infectious diseases	• It is expected to be used for the cancer treatments, particularly prostate cancer, and cardiovascular diseases like hypertension
siRNA technology	• siRNA based therapies have already shown great promise in treating ophthalmic diseases like macular degeneration and other eye diseases, as well as neurological diseases such as Alzheimer's and Parkinson's disease		• siRNA technology is expected to be used primarily for the treatment of metabolic disorders

02: CAPACITY BUILDING POLICY BRIEFS FOR BANGLADESH

Context

- The COVID-19 pandemic highlighted the challenge of inequitable access to vaccines, and led to calls for scaling domestic vaccine manufacturing in Bangladesh
- The ensuing transition from Gavi support by 2029 and graduation from the Least Developed Country (LDC) list in 2026 has triggered the increased need for self-financing of Bangladesh's immunization program and implementation of the Trade Related Aspects of Intellectual Property Rights (TRIPS) provisions
- To attain Bangladesh's aim of achieving self-sufficiency by 2027 and become a vaccine exporter by 2030, Accenture helped develop policy recommendations across three priority areas

Approach

- ❑ Assessment of current landscape across the three priority areas through secondary research and stakeholder interviews
- ❑ Identifying leading practices and innovations across comparable and well performing countries
- ❑ Developing policy recommendations across components using insights from and co-creation with ADB and Bangladesh stakeholders and other experts

Priority areas for policy recommendations

Creating an **enabling environment for vaccine manufacturing** both fill-finish and bulk substrate manufacturing

Strengthening the **clinical trial ecosystem** for greater access to internal and international markets

Regulatory upgradation to help the National Regulatory Authority in achieving maturity level 3

A stronger vaccine manufacturing ecosystem can be established in Bangladesh, which allows manufacturers to ensure commercial viability while protecting existing commercial interests

Current situation and challenges in Bangladesh

IP protection
- Patent law reformed in 2022
- IP enforcement needs strengthening

Skilled workforce
- Experience in small molecules production
- Recognition of the need for capacity building

Market size and potential
- Large birth cohort (~3 Mn births/ year)
- EPI vaccine market close to USD 90 Mn per year

Regulatory environment
- DGDA maturity classified as ML2
- Some actions for regulatory strengthening identified

Trade policies
- Bangladesh has one of the highest effective tariffs
- NTMs are low

Other extrinsic factors
- No financial/tax incentives in place
- Clusters of biological manufacturing not present

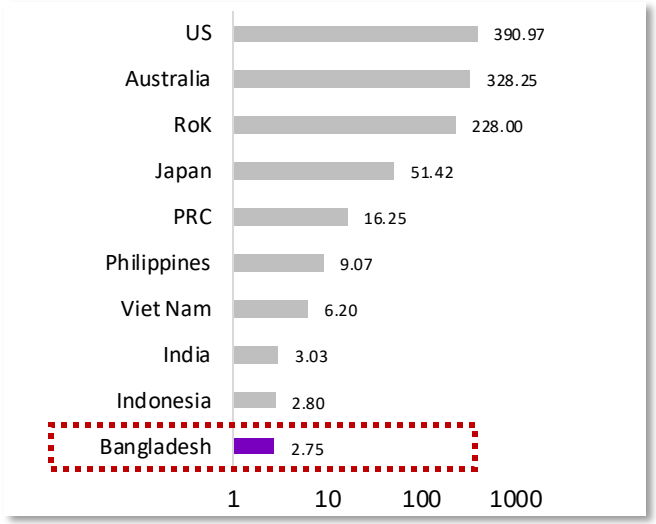
Recommendations

1	**IP Protection**	• Establish mechanisms for know-how protection within EDCL • Create early dispute settlement mechanism • Develop mechanisms for improved coordination for IP enforcement
2	**Skilled Workforce**	• Partner with NGOs and international institutes for on-site and remote trainings • Facilitate easy hiring and onboarding processes for expat workers • Establish training academies on vaccine manufacturing with pharma
3	**Market size and potential**	• Partner with vaccine manufacturers to create accurate forecasts of demand • Provide local market access and demand guarantees • Clearly define target export markets • Create mechanisms to prevent parallel imports of manufactured vaccines
4	**Regulatory environment**	• Create prioritized approval processes for products developed locally • Harmonize regulatory requirements for product approval and registration • Simplify recruitment processes and documentation for clinical trials • Develop regulatory capacity by investing in training programs
5	**Trade policies**	• Create policy to avoid export restrictions • Reduce remaining tariffs and streamline non-tariff measures • Establish mechanisms for co-operation between customs and other agencies • Ratify regional and continental trade agreements
6	**Other extrinsic factors**	• Develop an incentive framework to promote technology transfers • Provide production and/or capacity linked subsidies • Evaluate establishment of pharma parks, industrial parks, or special economic zones (SEZs)

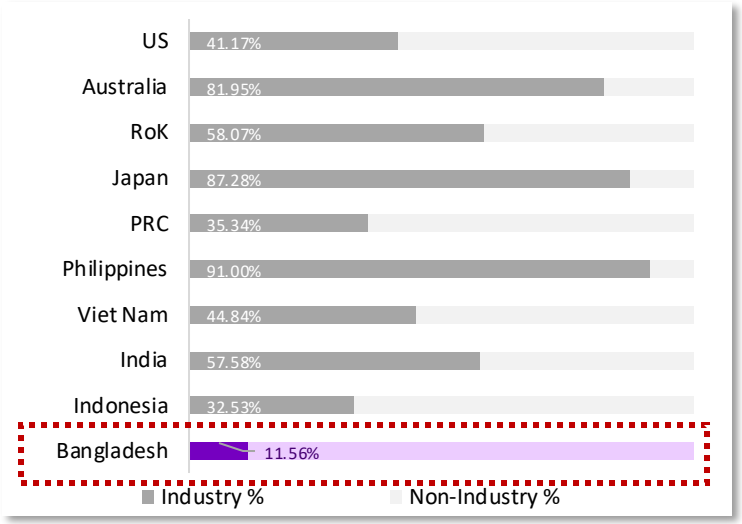
Clinical trial activity in Bangladesh is limited and concentrated at a few sites, and investments across the ecosystem are needed for streamlined clinical trial operations

Current situation and challenges in Bangladesh

Clinical trials per million, by country (2000-22)



Industry participation in clinical trials by country (2000-22)



- **Low presence of global CROs**
- **Limited clinical trial infrastructure**
- **Limited international collaboration and partnerships on clinical trials**
- **Taxation related and other financial incentives are not present**
- **Capacity building on clinical trials oversight is an identified need**
- **Opportunity for detailed guidelines on compensation and insurance**

Recommendations

1 Strengthen regulatory framework and optimize clinical trial processes

- Create policy for parallel ethics and regulatory reviews
- Standardize reporting requirements across trials
- Prioritized application processing for local applicants

2 Build clinical trial infrastructure and capacity

- Establish a pool of Principal Investigators (PI)
- Partner in international clinical networks
- Establish a network of clinical trial sites
- Create structured programs for capacity building of PIs

3 Prioritize data transparency and availability

- Drive uptake of electronic registry and record submission of PIs
- Make surveillance data and EHR data available to clinical trial organizations

As per best practices, improvement actions across the regulatory lifecycle are also required to strengthen the regulatory authority in Bangladesh

Current situation and challenges in Bangladesh

Pre-clinical and clinical research process
- Preclinical research regulatory framework not present
- Limited investments in capacity building
- Laboratory infrastructure is not well equipped

Registration and marketing authorization
- Lack of availability of clear SOPs for registration
- No official timelines for DGDA review
- Limited uptake of the electronic data systems
- Shortage of qualified inspectors in the DGDA

Manufacturing and quality control
- Inadequate funding, staffing shortages, and a lack of technical expertise
- NCL compliant with WHO recommended standards of Good Practices for PQCL

Supply chain management
- Good Distribution Practices (GDP) and Good Storage Practices (GSP) followed
- Procurement process for importing vaccines experiences delays
- Insufficient cold chain infrastructure

Post-market surveillance
- Inadequate surveillance and information data systems
- Shortage of IT-trained personnel
- No information regarding the use of E2B (R3) format for Case Safety Reports

Recommendations

1 Strengthen efforts towards harmonization to enhance regulatory frameworks and guidelines in Bangladesh
- Actively engage in regional and international initiatives for regulatory harmonization
- Align the structure and content of various modules in the regulatory dossier CTD format
- Establish formal partnerships through MoUs to facilitate collaboration, capacity building, and information sharing

2 Strengthen regulatory capacity building
- Develop a comprehensive workforce strengthening strategy and program
- Implement targeted recruitment efforts to attract highly skilled professionals
- Develop a central training facility to orient new staff members on regulatory activities and provide specialized training

3 Prioritize investments in infrastructure and IT capabilities
- Improve laboratory infrastructure to get GLP accreditation for reliable testing of products
- Upgrade storage facilities and supply chain management guidelines
- Leverage electronic information management systems to improve transparency and streamline regulatory processes

4 Increase implementation and effectiveness of key regulatory functions
- Establish clear and transparent timelines for critical regulatory processes
- Improve the pharmacovigilance/post-marketing surveillance (PV/PMS) mechanism and infrastructure
- Implement a self-assessment system within the DGDA

ADB published these detailed insights and recommendations into three policy briefs focused on Bangladesh in May 2024

Creating an Enabling Environment for Vaccine Manufacturing in Bangladesh

Strengthening the Clinical Trials Ecosystem in Bangladesh

Strengthening the Regulatory Ecosystem for Vaccines

Available at www.adb.org/publications

Thank You

